

BMJ Open Patient journey following lumbar discectomy surgery: protocol for a single-centre qualitative analysis of the patient rehabilitation experience (DiscJourn)

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ABSTRACT

Introduction Lumbar discectomy is a widely used surgical procedure internationally with the majority of patients experiencing significant benefit. However, approximately 20% of patients report suboptimal functional recovery and quality of life. The impact and meaning of the surgical experience from the patients' perspective are not fully understood. Furthermore, there is limited evidence guiding postoperative management with significant clinical practice variation and it is unclear if current postoperative support is valued, beneficial or meets patients' needs and expectations. This study aims to address the evidence gap by moving beyond current knowledge to gain insight into the lived experiences relating to patients' lumbar discectomy surgery journey. Results will inform more meaningful and specific care, thus, enhance rehabilitation and outcomes.

Methods and analysis A qualitative investigation using interpretative phenomenology analysis (IPA) will provide a flexible inductive research approach. A purposive sample (n=20) of patients undergoing primary discectomy will be recruited from one UK NHS secondary care centre. Semi-structured interviews will be conducted postsurgery discharge. A topic guide, developed from the literature and our previous work with input from two patient co-investigators, will guide interviews with the flexibility to explore interesting or patient-specific points raised. Providing longitudinal data, patients will keep weekly diaries capturing experiences and change over time throughout 12 months following surgery. A second interview will be completed 1 year postsurgery with its topic guide informed by initial findings. This combination of patient interviews and diaries will capture patients' attitudes and beliefs regarding surgery and recovery, facilitators and barriers to progress, experiences regarding return to activities/function and interactions with healthcare professionals. The rich density of data will be thematically analysed in accordance with IPA, supported by NVivo software.

Ethics and dissemination Ethical approval has been granted by the London-Bloomsbury Research Ethics Committee (18/LO/0459; IRAS 241345). Conclusions will be disseminated through conferences and peer-reviewed journals.

Strengths and limitations of this study

- This qualitative study offers a unique in-depth understanding of the patient journey providing insight into what is important to patients' recovery following lumbar discectomy surgery.
- Findings will inform future clinical practice with specific and meaningful rehabilitation based on patient needs.
- This is the first longitudinal qualitative study tracking patients throughout the initial postoperative year.
- A limitation is that the study is single centre and patient experiences may vary across regions, although themes and participant accounts will be transferable to other patients in similar contexts.
- Findings will complement existing quantitative conclusions extending the postlumbar discectomy evidence base.

INTRODUCTION

Lumbar discectomy is the most common spinal surgical procedure in the UK¹ and the USA.^{2,3} In the UK, 3744 primary lumbar discectomies and an additional 10568 primary lumbar decompression procedures were performed in 2016–2017. In the USA, 438 211 inpatient stays for laminectomy and excision of intervertebral disc were recorded in 2014.⁴ Lumbar discectomy is an effective treatment for persistent disabling sciatic pain with evidence of faster symptomatic relief compared with conservative management.³ Discectomy surgery is also effective for disabling neurological function due to lumbar disc nerve compression in emergency situations, this can include compression of the cauda equina nerves controlling bowel, bladder and sexual functioning.^{5–7} However, there is limited understanding of patients' experiences; the impact of the

surgery itself, postoperative recovery and the effect of persistent symptoms and disabilities on patients' lives. The aim of this qualitative study is to explore patients' experiences through the first postsurgery year to inform practice changes towards the improved evidence-based patient-centred care and outcomes.

The majority of patients undergoing discectomy experience benefit with significant improvements in pain (leg pain more than back pain)^{3 5 8} and disability.⁹ Moreover, perceived recovery post discectomy has been reported by 79%–95% of patients^{10 11} with around 80% of patient expectations met following surgery¹² and recovery at 1 and 2 years.¹³ However, not all patients experience complete symptom resolution and return to full function; a systematic review reported residual leg pain and disability 5 years postsurgery⁹ and 4% of patients described postsurgery worsening.¹⁴ Persistent motor deficit, lower quality of life scores⁸ and recurrent disc protrusions requiring revision surgery^{15 16} have also been documented with an array of biopsychosocial factors (including pain severity and work-related dissatisfaction) reported in systematic reviews.^{17 18} Greater understanding of the patient experience is required to provide insight into the meaning of the surgical experience to patients' lives and to deepen our understanding of why some patients' outcomes are better than others.

Limited qualitative studies have been undertaken, to date, following lumbar discectomy surgery. One study focused on perceptions of outpatient surgery¹⁹ and another investigated what patients felt they could do postsurgery.²⁰ A further focus group study involved retrospective recall of experiences 1-year postsurgery (n=7), but included patients undergoing wider surgery for discogenic compression and stenosis.²¹ A focus group study was also completed by our group finding different views between patient and physiotherapist participants regarding perceived postsurgery rehabilitation needs.²²

Taking a wider view of qualitative investigations, a systematic review found that the patient experience was positively associated with clinical effectiveness as well as patient safety.²³ Furthermore, health policy recommends understanding experience from the patient perspective as essential to inform high-quality, patient-centred care.²⁴ Similar qualitative studies have been undertaken in other areas^{25–27} with results informing practice improvement recommendations using the insight gained from patient experiences not previously recognised or, therefore, addressed.

Within the literature, there is low/very low-quality evidence supporting rehabilitation with high-intensity exercise programmes starting 4–6 weeks postsurgery demonstrating the potential to improve pain and disability,²⁸ and movement and physical impairment²⁹ in the short-term. Furthermore, it remains unclear if *all* patients require intensive postdiscectomy rehabilitation.

Evidence also highlights variation in postdiscectomy management (including referral to physiotherapy content, advice and guidance offered)^{10 30 31} and survey

results³¹ showed lack of consistency in postoperative advice with restricted activities, including sitting, lifting, return to work and driving, advocated for a variety of postoperative periods. Several studies also challenge the need for postlumbar discectomy restrictions^{32–34} with a single-blinded randomised controlled trial now underway.³⁵ Current practice inconsistencies may reflect the limited evidence guiding clinicians resulting in lack of consensus. This qualitative study will explore patients' postoperative experiences providing insight into rehabilitation content and perceived postdiscectomy needs, as well as facilitators and barriers to progress, which, in turn, will inform more targeted care based on needs identified by patients themselves.

Within the non-surgical back pain literature, there is evidence that healthcare professionals inadvertently contribute to back pain-related disability³⁶ with exposure to healthcare sometimes producing harmful effects. A long-term postdiscectomy analysis³⁷ found that only 40% of patients continued recreational activities, including sports, undertaken presurgery.

Another qualitative investigation²⁰ undertook semi-structured interviews, finding high levels of postoperative anxiety related to restricted postoperative movement and suboptimal recovery, and that the physiotherapists did not help participants to fully explore their potential for activity. The influence of healthcare providers within postdiscectomy management is not fully understood.

To the best of our knowledge, this study is the first to undertake patient interviews and track patients throughout the first postdiscectomy year, thus providing rich longitudinal data and detailed insight into the patients' experience related to the lumbar discectomy journey. This is important as surgical success (ie, achieving optimal outcomes following surgery) appears to be complex and multifactorial and at present, it is not fully understood why some patients' recovery and outcomes are better than others. Insight into patients' views, perceptions, experiences and expectations will enhance clinicians' ability to better address what is important from the patients' perspective and enable care providers to fully address postdiscectomy needs as identified by the individual patient themselves.

Aim

To gain insight and understanding of patients' perceptions and lived experiences relating to their lumbar discectomy surgery journey.

Objectives

1. To explore the patient journey following surgery and understand their experiences, including perceptions related to lower back and leg symptoms experienced, strategies/mechanisms employed to cope and manage symptoms, reflections regarding factors influencing the decision to pursue surgery, perceptions and

management relating to symptomatology and function associated with lumbar discectomy surgery.

2. To understand the patient journey through to their return to functional activities and previous everyday life.
3. To explore barriers and facilitators affecting recovery.
4. To explore the patients' perspective regarding the stages/components of the discectomy journey.
5. To explore similarities and differences between patients/patient groups (eg, emergency vs elective surgery).
6. To explore patient-perceived postsurgery rehabilitation requirements, perceptions of the value of and adherence to physiotherapy received as well as the role of physiotherapy in managing persistent or recurrent symptoms.
7. To inform rehabilitation based on evaluation of patient needs identified through improved understanding of the patient journey.

Additionally

Patients involved in this study will be asked to document their own patient and public involvement (PPI) experience in order to share good practice and improve future work.

Rationale

Clinicians can use patient-reported outcome measures to complement clinical observations and testing to better understand impairments and disabilities. However, it is only patients themselves who can report their symptoms and quality of life as well as reflect on their own individual experiences and expectations in relation to their own framework, values and care experience. Similar qualitative investigations undertaken in other areas demonstrate the value of gaining insight into the patients' world. This qualitative study using semi-structured interviews and patient diaries will be undertaken to gain insight across all aspects of the discectomy care pathway through the patient's lens. With large patient numbers undergoing discectomy annually, it is important that recovery is optimised, both from a patient and economic perspective. Findings from this study will assist clinicians to address issues that are important from the patients' perspective towards improved postdiscectomy care, satisfaction and outcomes.

METHODS AND ANALYSIS

Theoretical framework

A phenomenology framework using interpretative phenomenological analysis (IPA) was selected to explore patients' experience of the lumbar discectomy journey. This framework enables exploration of the experience of the surgery and postoperative recovery with an important interpretative component to deepen understanding of the meaning and making sense of the experience for the individual. Drawing on our groups' previous research and clinical work, convergence and divergence in patients'

experiences and responses to surgery evolved stimulating development of this study. Furthermore, relating this professional and theoretical knowledge and experience will enable analysis and development of theoretical generalisability³⁸ (p. 2–5).

Study design

Qualitative research employing IPA³⁸ provides a flexible inductive research approach. IPA was initially developed by Husserl in psychology research and progressed by Heidegger.³⁸ It combines phenomenology (description of an experience or phenomenon) with hermeneutics (interpreting or making sense of the experience). It acknowledges that people are actively engaged in making sense of their experiences and therefore, IPA researchers attempt to understand what it is like to 'stand in the participant's shoes'. IPA is, therefore, a dynamic process with interpretative activities making meaning (participant's account) and sense (researcher decoding) of an experience from the patients' perspective, that is, a combination of description and interpretation.

IPA is also idiographic, meaning that single cases will be analysed in-depth and individual experiences will be examined with analysis of data through considering the meaning of experience of individual patient journeys. Themes emerging across individual participants provide valuable insight into differences and similarities of individual patient journeys as well as barriers to achieving optimal functional recovery. The unique patient-specific view of the experience may provide unexpected aspects of the journey not 'visible' to the clinician. This idiography means that the study findings will not be generalisable to all patients undergoing lumbar discectomy. However, through analysis and emerging themes, participants' accounts will be transferable to other patients in similar contexts. In addition, clinicians can link IPA study analysis with their own personal and professional experiences as well as with the existing evidence base³⁸ (p. 51).

Study setting

One secondary care setting (Queen Elizabeth Hospital (QEHB)), University Hospitals Birmingham NHS Foundation Trust) which is a large teaching hospital with a regional neurosurgical specialty.

Methods

Two methods will be incorporated into this study, including semi-structured interviews and patient diaries.

In-depth semi-structured interviews

Two semi-structured interviews will be undertaken for each participant. The first will be completed in the initial postoperative period following discharge home (1–3 weeks postsurgery) with the second interview completed 12 months following surgery. Participants will be given the choice regarding whether interviews are undertaken within QEHB or at home. Consenting participants will be offered a time convenient to them and, where possible, interviews within the hospital will be arranged to coincide

with other postsurgery appointments to avoid additional journeys.

Following informed consent, interviews will be conducted by the Trust principal investigator (PI) who has clinical expertise in this area. To limit bias, the PI will not provide therapy for participants and although they will be aware that the interviewer is a physiotherapist, the clinical uniform will not be worn during the interviews. On the basis of previous experience, it is predicted that the interview duration will be approximately 60 min. The interviewer will follow a topic guide developed from systematic reviews, surveys and an audit of current practice^{28–31 39} with input from our two patient co-investigators. The topic guide is also developed and aligned to that of a parallel study investigating lumbar fusion surgery.⁴⁰ Although it provides a framework for interview discussions, participants will also be actively encouraged to discuss additional issues/new topics specific to them within the interview. This format aims to prompt and capture *individual* journeys by allowing flexibility within the interview with topic guide questions exploring both preoperative and postoperative experiences, including participant's expectations from surgery, underlying attitudes and beliefs towards the surgical intervention, facilitators and barriers to recovery, adherence to advice and physiotherapy, experiences of rehabilitation, and return to previous function, activity and/or work. Similarities and differences between patients/patient groups, such as those undergoing elective versus emergency surgery, will be analysed. A topic guide will be constructed for the second interview process from the analysis of the first interview and patient diary data.

Prior to commencing the interview, the interviewer will make clear to participants that involvement in the interview is entirely voluntary and that the interview can be stopped at any time at their request. The interviewer will endeavour to create a relaxed and comfortable environment and, for example, will engage the participant in general conversation. This will also enable the interviewer to check the participants' well-being. If participant distress occurs during the interview, appropriate action will be taken, for example, stopping the interview and establishing if further participant support is required.

An encrypted data recorder will be utilised to audio-record interviews and data will be transcribed verbatim. The interviewer will also take field notes to supplement recordings and will complete a reflexive diary. Participants will be offered the opportunity to read through transcriptions and add any further comments or reflections. Dependent on a participant's preference, this process will be undertaken by post or email with a discussion regarding content also offered using telephone or Skype.

Twelve-month written or electronic patient diary

To complement and enhance the depth of the data gleaned from patient interviews, patient diaries will be included. There is recognition regarding the value of patient diaries. However, potential issues with participant

adherence to diary completion are acknowledged with other methods considered (eg, serial interviews) to explore change over time and provide longitudinal data. Due to time and resource restrictions, diaries were used with various methods of data collection to be offered to enhance compliance. A growing preference for electronic rather than paper data collection is reported,⁴¹ which is consistent with the findings from our recent postlumbar discectomy focus groups.³¹ Participants can, therefore, choose between various diary media, including structured paper/email or audio (using existing mobile/tablet technology) diaries with weekly entries made. To improve adherence, weekly prompts (text, email or telephone, according to patient's preference) to remind them regarding completion will be undertaken, with monthly diary collection (post or email) enabling discussion regarding progress and evaluation of ongoing adherence.

Patient diary entries will provide longitudinal data to capture symptoms, medication, critical moments and experiences of stages of recovery, rehabilitation adherence, healthcare professional appointments, attitudes and participants' feelings throughout their journey. This process will, therefore, provide real-time participant data, tracking the course of patients' experiences over time.

Study participants

A purposive sample will be recruited to 'access the participant's personal world'³⁸ (p. 218) As required for IPA design, participants will represent a homogenous population relating to the topic of investigation,³⁸ that is, lumbar discectomy for radiculopathy and/or cauda equina dysfunction due to discogenic neural compression.^{5–7} To enable exploration of participant similarities and differences, a sufficiently large sample size is required to ensure inclusion of a range of ages, ethnicity, gender⁴² and other factors identified as influencing lumbar disc surgery outcomes (including level of education, preoperative pain level, work satisfaction, sick leave duration from work, co-existing psychological issues and coping strategies).^{17 18}

The IPA method involves a joint process between the patient and the researcher to make sense and analyse experiences. It, therefore, requires that the participant is able to articulate their experiences and thoughts and that the researcher is able to reflect on and analyse the information offered.⁴³ Guest *et al*⁴⁴ have reported data saturation after 12 interviews. Within this study, the precise number of participants will be determined during the study and recruitment will continue until saturation is reached, that is, when data ceases to identify new themes. However, it is anticipated that 20 participants will be required to ensure an adequate number of participants complete patient diaries and second interviews. Feasibility assessment has indicated that this sample size is well within annual data (>300 lumbar discectomy procedures undertaken annually at QEHB). This sample size will constantly be reviewed during the study to ensure that the density of evidence is achieved with adequate

quality and quantity of data captured to enable analysis and identification of similarities and differences in experiences.

Participant eligibility criteria

Inclusion criteria: Adult patients (≥ 16 years) undergoing elective or emergency primary lumbar discectomy surgery, willing to provide written informed consent and able to communicate in English.

Exclusion criteria: malignancy, infection, poor English or communication difficulties.

Sample identification

Participants will be recruited from patients undergoing lumbar discectomy. Patients undergoing NHS surgery as part of a waiting list initiative in a private hospital setting will also be considered. Potential participants will be identified by several members of the neurosurgery team (including Trust PI (LW), surgeons, ward physiotherapist or the waiting list coordinator team). Surgery will be elective or emergency (eg, including patients requiring surgery for cauda equina compression). Elective surgery patients will be introduced to the study when offered surgical intervention in the outpatient clinic, where a copy of the participant information sheet will be provided. Following this introduction, suitable patients will be contacted by the PI to discuss inclusion in the study. The participant information sheet will be discussed, and any questions about the study answered. At this point, the patient will be asked for permission to contact them again approximately 2 weeks prior to admission to discuss any questions they may have regarding the study. The PI will confirm patients interested in study participation with the waiting list coordinator who will then alert the PI of appropriate patients 2 weeks prior to admission. Patients undergoing emergency surgery will be identified by ward staff and introduced to the study during admission using the participant information sheet. The PI will then seek informed consent. The diary will be introduced and explained at recruitment, thus allowing time for participants to become familiar with this component of the study prior to the initial interview, where again the diary will be discussed. The PI will contact all consenting patients following discharge home to commence the patient diary and arrange the first interview. The patient will subsequently be contacted to arrange the 12-month interviews.

Consent

Consent to participate in the study will be sought during admission—either preoperatively or postoperatively—and therefore, the patient is not inconvenienced by additional hospital visits. The PI or recruiting ward physiotherapist will undertake consent for the study; both have current Good Clinical Practice (GCP) training as well as the necessary experience and skills to ensure patients have adequate capacity to provide informed consent.

Data analysis

IPA involves analysis of data by considering the meaning of experience⁴⁵ and is suited to healthcare research as it encompasses a holistic approach, including biopsychosocial theories and aspects of the presentation. The interviewer will primarily analyse the data and during this process will attempt to suspend all judgements and presuppositions.⁴⁵ However, to ensure rigour of analysis, four stages will be undertaken.

Stage 1

Interviews will be transcribed verbatim and will include detail of non-verbal content (eg, speech dynamics⁴⁵). The PI will review the transcribed text and audio-recordings with field notes.

Stage 2

Preliminary themes will be identified and presented first to investigator AM (conducting data analysis parallel study⁴⁰) and then the study management group (including patient co-investigators) for discussion. Data will be coded in accordance with IPA.³⁸ An initial analysis phase of the first six interviews will enable the data analyses, purposive sampling and topic guide to be evaluated by the study management group.

Stages 3 and 4

The PI and blind reviewer will independently group themes together as clusters and tabulate in a summary table, illustrated by verbatim extracts.⁴³ Data management will be supported through NVivo software. Co-investigator AM will critique with discussion to consider for a priori concepts. Themes in a summary table will be constructed to include evolving themes and will be discussed with patient co-investigators and the study management group. Halkier⁴⁶ describes three different methods to enable analytical generalisations which will be incorporated in analyses. These include ideal typologising (condensing the coded data into emerging patterns of similarities and differences relating to one particular typology); category zooming, which focusses on one particular point providing depth of understanding relating to the issue in question; and positioning, which is complex and dynamic encompassing the social context (interaction with others) with knowledge and beliefs. The analysis will draw on researchers' knowledge, previous research and clinical experience to enable interpretation of the patients' experiences and engage with participant reflections to reveal clinically meaningful guidance.

Strategies to ensure trustworthiness will include considering data to the detail of minor themes, independent coding from three experienced researchers, peer and patient critique and review, code-recode audits, a constant comparative process, acknowledgement of the researchers' preconceptions and beliefs, and active reflexivity to enable greater transparency.^{43 47} A collaborative approach to the analysis representing professional

and PPI perspectives aims to enhance researcher reflexivity, and hence quality of the analysis.⁴⁷

The same format will be used for the analysis of the patient diaries. Audio diaries will be transcribed verbatim and incorporated with written diary entries. Results from the diary analysis and semi-structured interviews will provide breadth and depth of data on which to develop second interviews.

Implications of results

While discectomy surgery can offer immediate relief of pain and neurological deterioration, the effect on the individual and their 'life' is not well understood. Deeper understanding and making sense of the patients' experiences will extend knowledge regarding what is important to patients during their first postdiscectomy year. Exposing experiences, perceptions and beliefs and considering the content and value of therapeutic interventions will shape changes to postlumbar discectomy care based on patient-perceived needs. Valuable understanding of barriers and facilitators affecting outcomes and strategies patients' use to manage and cope with persistent postoperative problems will also be better understood. Clinicians can, therefore, alter clinical practice providing meaningful and specific interventions following lumbar discectomy based on needs identified by patients themselves, thus enhancing future patient experiences, management and outcomes.

Research governance

The study will comply with the principles of the Research Governance Framework for Health and Social Care.⁴⁸ GCP protocols and principles will be implemented throughout the study. Patient confidentiality will be maintained and anonymised data stored confidentially in accordance with the Data Protection Act (DPA) and the General Data Protection Regulation (GDPR) (2018) as well as complying with the University of Birmingham and QEHb research governance frameworks for 10 years. The study management group will review the study progress and analysis to inform data interpretation. A low risk for the study is not recruiting enough participants, and if this occurs then recruitment time will be extended.

Patient and public involvement

The patient perspective is central to this study which is reflected in the selected design using IPA. Involvement of patient representatives is, therefore, invaluable with recognition of the growing value of patient representation within the literature.⁴⁹ Development of this research project has included patients and clinicians with patient representation from inception. The interview topic guide, patient diaries, participant information sheet and consent form have all been compiled with patient contributions. Patient representatives will also be involved in the analysis and within the study management groups.

One patient representative has been involved with the team for >5 years and has contributed to previous work

relating to lumbar discectomy. Our second patient representative has undergone surgery recently, and therefore provides highly relevant recent experience. As co-investigators working within the research team, both patient representatives provide insight into the study design with future involvement including interpretation of results and production of a lay summary of the findings. Patient representatives will be asked to record their own 'PPI' experiences relating to the project to document their unique perspective and influence within the project.

Ethics and dissemination

Minimal risks are associated with this study. However, it is possible that the participants may disclose information of concern regarding their well-being to the researcher during interviews or the researcher may observe areas of concern. If such situations were to arise then safeguarding mechanisms would be employed to ensure the well-being of the participant. With discussion and consent from the participant, the site clinical team would be notified to ensure an appropriate plan which was agreed to address the highlighted issues.

The DPA and GDPR 2018 will be adhered to in relation to collection, storage, processing and disclosure of personal information by all research and clinical staff involved in the project. Password-protected computers will be used to store personal information collected and participant identifying information will be replaced by unrelated sequence of characters and data will be coded and de-personalised. Secure maintenance of the data will ensure that the linking code is kept securely in a separate location using encrypted digital files within password-protected folders and storage media. Only the chief investigator, co-investigator (AM) and Trust PI, carrying out the interviews, will have access to the data as necessary for the quality, audit and analysis. Data will then be stored for 10 years as required for compliance with sponsor research governance and the chief investigator (AR) will be the data custodian. Any breaches to the protocol or of confidentiality will be documented on relevant forms and reported to AR and sponsor (University of Birmingham) immediately.

The study results will be disseminated for publication in peer-reviewed journals with presentation at appropriate international conferences.

PEER REVIEW

A parallel study protocol⁴⁰ has undergone an independent, high-quality and proportionate peer review from its funder. This study uses a similar qualitative design within the lumbar discectomy patient population and has been undertaken within the framework of the Masters to Doctorate Bridging Programme, which is commissioned by the Health Education England/West Midlands. The programme is hosted by the National Institute for Health Research/Wellcome Trust Clinical Research Facility at

the University Hospitals Birmingham NHS Foundation Trust.

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Contributors LW is the clinical site principal investigator leading protocol development, approvals, analyses and dissemination. ABR is the chief investigator overseeing study design and quality. ABR, NRH and AM led on a parallel study protocol on which this study was first based. LW, ABR, NRH, AM and NF have led on conception, design and overseeing data analysis. LW, ABR, NRH and AM will lead the interpretation and synthesis of findings, and conclusions. All the authors have contributed to methodological decisions. All the authors will contribute to dissemination. LW drafted the manuscript. All the reviewers have read, contributed to and agreed to the final manuscript. ABR is the guarantor.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethical approval granted by the London-Bloomsbury Research Ethics Committee (18/LO/0459). HRA approval granted (protocol number RG_18-029; IRAS project number 241345). NHS site confirmation of capacity and capability have been obtained.

Provenance and peer review Non-commissioned; peer-reviewed for ethical approval prior to submission.

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