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TITLE

The patient journey following lumbar discectomy surgery: protocol for a single centre qualitative analysis of the patient experience (DiscJourn)

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ABSTRACT

Introduction

Lumbar discectomy is a widely used surgical procedure internationally with most patients experiencing significant benefit. However, for some the outcome is unsatisfactory with approximately 20% patients reporting sub-optimal functional recovery and quality of life. Although recommended, post-discectomy management and rehabilitation varies considerably and there is limited guidance for clinicians with little known about the patients' experience. Understanding the patient journey will enhance a clinician's ability to offer precision advice and rehabilitation to optimise recovery. The aim of this study is to gain understanding of patients' perceptions and capture lived experiences relating to their lumbar discectomy surgery journey.

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. Study design is informed by the Consolidated Criteria for Reporting Qualitative Studies. Semi-structured interviews will be conducted post-surgery discharge. A topic guide, developed from literature, our previous work, and our two patient co-investigators, will guide the interviews with flexibility to explore interesting or participant specific points raised. Adding further "real time" details of the journey lived, patients will keep weekly diaries providing their real-time experience over 12 months. A second interview will be completed one year post-surgery with its topic guide informed by initial findings.

This novel 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). The study conclusions will be disseminated through conferences and peer-reviewed journals.

ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This qualitative study offers unique and in-depth understanding of the patient journey post lumbar discectomy surgery.
- Greater understanding of what is important to the patient will inform future clinical practice and precision rehabilitation based on patient needs.
- This is the first qualitative study to track patients throughout the initial post-operative year.
- A limitation is that the study is single centre and patient experiences may vary across centres.
- The study design was informed by the Consolidated Criteria for Reporting Qualitative Research (COREQ) to ensure rigorous design.

INTRODUCTION

Lumbar discectomy is undertaken to alleviate refractory leg pain with or without progressive lower limb weakness due to discogenic nerve root compression (radiculopathy). It is also used in emergency situations when there is neurological dysfunction due to discogenic cauda equina compression[1-3]. Discectomy is the most common spinal surgical procedure in the UK[4] and USA[5-6] with 3744 primary lumbar discectomies and an additional 10568 primary lumbar decompression procedures performed in the UK in 2016-2017. In the USA, 438 211 inpatient stays for laminectomy and excision of intervertebral disc were recorded in 2014[7].

The majority of patients undergoing discectomy surgery experience benefit with significant improvements in pain (leg pain more than back pain)[3,6,8] 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 surgery[12] and recovery at 1 and 2 years[13]. Despite these positive results, post-operative recovery for a substantial number of patients is less than satisfactory, with a systematic review reporting residual leg pain and disability 5 years post-surgery[9] and 4% of patients describing post-surgery worsening[14]. Persistent motor deficit, lower quality of life scores[8], and recurrent disc protrusions requiring revision surgery[15,16] have also been documented. Factors which may influence patient outcomes have not yet been established with biophysical, psychological and social factors (including pain severity, work related dissatisfaction) reported in systematic reviews[17,18]. Whilst there is a clear need for more high quality research, it remains unclear what patients perceive are key factors affecting outcomes and limiting expectations.

Surgical outcomes may also be influenced by current management. Evidence shows variation in post-discectomy management and rehabilitation within the UK and the Netherlands in terms of

referral to physiotherapy as well as content, advice and guidance offered[10,19,20]. Such inconsistency of practice may reflect the limited available evidence to guide clinicians. In addition, there is low/very low quality evidence supporting rehabilitation intervention through high intensity exercise programmes starting 4-6 weeks post-surgery with potential to improve pain and disability[21], movement and physical impairment[22] in the short term. However, it is not clear if *all* patients require intensive post-discectomy rehabilitation; and further exploration of individual post-operative journeys will therefore provide more insight into patient experiences and perceived post-surgery requirements as well as explore how patients' value and adhere to rehabilitation.

There is evidence that healthcare professionals inadvertently contribute to back pain related disability[23] in the non-surgical lower back pain population with exposure to healthcare sometimes producing harmful effects. It is possible that this also occurs post-discectomy; a long term post-discectomy analysis[24] found that only 40% of patients continued recreational activities, including sports, undertaken pre-surgery and it is possible that clinicians contribute to such functional limitation post-discectomy. Also survey results[20] showed lack of consistency in post-operative advice with restricted activities including sitting, lifting, return to work, driving advocated for a variety of post-operative periods with this lack of consensus also potentially adding to confusion. Furthermore, it is possible that post-operative restrictions are in fact not required, with several studies beginning to explore the effects of no post-lumbar discectomy restrictions[25-27] and results showing no increase in post-operative complications. A single blinded randomised controlled trial is now underway[28]to investigate this further. Exploration of patients' current post-operative return to function and activities as well as patients' interpretation of advice and information offered, beliefs affecting behavior will thus provide important insight into current facilitators and barriers to progress and functional recovery.

Limited qualitative studies have been undertaken within the lumbar discectomy patient group to date; one study focused on perceptions of out-patient surgery[29]. Another conducted 2 focus groups (n=7) 1 year post surgery but this involved retrospective recall of experiences and included

patients undergoing surgery for discogenic compression and stenosis[30]. A focus group study was also undertaken by our group to particularly explore patient and physiotherapists perspectives of a patient information leaflet and individualised physiotherapy post lumbar discectomy[31]. A further qualitative investigation completed semi-structured interviews to investigate what patients felt they could do post lumbar discectomy[32]. However, this study is the first to undertake patient interviews and to track patients throughout the first post-discectomy year thus providing "real-time" and detailed insight into the patients' experience related to the entire primary lumbar discectomy journey. This is important as it is recognised that surgical "success" appears to be complex and multifactorial and at present it is not fully understood why some patients' recovery and outcomes are better than others. The evidence indicates physical and psychosocial factors but gaining insight into patients' views, perceptions, experiences and expectations will enhance a clinician's ability to better address what is important from the patients' perspective and enable care providers to fully address post-discectomy needs as identified by the individual patient themselves.

Aim

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

Objectives

1. To explore the patient journey and understand their experiences including perceptions related to lower back and leg symptoms experienced, strategies/ mechanisms employed to cope and manage symptoms, factors influencing the decision to pursue surgery, perceptions and management in relation to symptomatology and function pre and post lumbar discectomy surgery.

2. To understand the patient journey through to their return to functional activities and previous lifestyle including exploration of barriers and facilitators.

3. To explore the patient's perspective regarding the stages/ components of the discectomy journey.

4. To explore similarities and differences between patients/ patient groups (e.g. emergency versus elective surgery).

5. To explore patient perceived post-surgery 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.

6. To inform precision rehabilitation based on evaluation of patient needs identified through improved understanding of the patient journey.

Additionally:

The patients involved in this study will be asked to document their own Patient and Public involvement experience (PPIE) 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 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. Therefore, a 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 post-operative recovery is optimised, both from a patient and economic perspective and the results of this study will assist clinicians to address

issues that are important from the patients' perspective towards improved post-discectomy satisfaction and outcomes.

METHODS AND ANALYSIS:

Theoretical framework

Interpretive Phenomenological Analysis (IPA) approach.

Study design

Qualitative research employing IPA[33] provides a flexible inductive research approach. It involves analysis of data by considering the meaning of experience and provides valuable insight into the differences and similarities with individual patient journeys, exploring barriers to progress and achieving optimal functional recovery. Study design was informed by the Consolidated Criteria for Reporting Qualitative Studies[34]. Patient views provide clinicians with insight into recovery from their own perspective thus providing a unique view of the experience which may provide unexpected aspects of the journey not "visible" to the clinician.

Study Setting

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

Methods

In-depth semi-structured interviews

Two semi-structured interviews will be undertaken. The first interview will be undertaken in the initial post-operative period following discharge home. The second interview will be completed 12 months following surgery. Participants will be given the choice regarding whether the interviews will

be undertaken within QEHB or within their home. Consenting participants will be offered a time convenient to them and, if the interview is at QEHB, where possible, interviews will be arranged to coincide with other post-surgery appointments to avoid additional journeys.

Following informed consent, interviews will be conducted by the PI who has clinical expertise in this area. Based on previous experience, it is predicted that interview duration will be approximately 60 minutes. The interviewer will follow a topic guide developed from systematic reviews, surveys and an audit of current practice[19-22,35] with input from our 2 patient co-investigators. The topic guide is also developed and aligned to that of a parallel study investigating lumbar spinal fusion surgery[36]. Participants will also be actively encouraged to discuss additional issues/ new topics specific to them within the interview. The aim is to prompt and capture their individual journeys with topic guide questions exploring both pre- and post-operative 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 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 endevour to create a relaxed and comfortable environment for the interview and for example, will engage the participant in general conversation. This will also enable the interviewer to check the participants' wellbeing. 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 though transcriptions and add any further comments or reflections. Dependent on a participant's preference, this process will be undertaken by post or email with discussion regarding content also offered using telephone or Skype.

12-month written or electronic patient diary

To complement and enhance the depth of the data gleaned from patient interviews, patient diaries will be used. There is recognition regarding the value of patient diaries, but questions are raised within the literature regarding participant adherence and quality of data captured. In addition, the literature suggests growing preference for electronic rather than paper data collection[37]; which is consistent with findings from our recent post lumbar discectomy focus groups[31] with diversity of preference between electronic versus paper data interaction/ collection. 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 diary 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, experiences of stages of recovery, rehabilitation adherence, healthcare professional appointments, attitudes and participants' feelings throughout their journey. This process will therefore capture real time participant data, tracking the course of patients' experiences over time.

Study Participants

A purposive sample will be recruited and participants' experiences captured. This process will provide "access (to) the participant's personal world" (Smith p218)[33] and will offer insight into their experiences during the pre-surgical, admission and post-surgical phases. As required for IPA design, participants will represent a homogenous population relating to the topic of investigation[33] i.e. lumbar discectomy for radiculopathy and/or cauda equina dysfunction due to discogenic neural compression[1-3]. To enable exploration of participant similarities and differences, a sufficiently large sample size is required to ensure inclusion of a range of ages, ethnicity, gender[38] and other factors identified as influencing lumbar disc surgery outcomes (including level of education, pre-operative pain level, work satisfaction, sick leave duration from work, co-existing psychological issues, coping strategies)[17-18].

The IPA method involves a joint process between the patient and 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[39]. Guest et al[40] have reported data saturation after 12 interviews. 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 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. 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 (e.g. 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 will be 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 the participant 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 pre or post operatively- 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 the patient has adequate capacity to provide informed consent.

Data analysis

IPA involves analysis of data by considering the meaning of experience[41] and is suited to health care 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[41]. However, to ensure rigor of analysis, 4 stages will be undertaken:

Stage 1: Interviews will be transcribed verbatim and will include detail of non-verbal content (e.g. speech dynamics[41]). The PI (LW) will review the transcribed text and audio recordings with field notes.

Stage 2: Preliminary themes will be identified and presented firstly to investigator AM (conducting data analysis parallel study[36] and then the Study Management Group (including patient co-investigators) for discussion. Data will be coded in accordance with IPA[33]. An initial analysis phase of the first 6 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 (LW) and blind reviewer will independently group themes together as clusters and tabulate in a summary table, illustrated by verbatim extracts[39]. 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 then with the study management group.

Strategies to ensure trustworthiness will include considering data to the detail of minor themes, blind coding from 3 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[39,42]. A collaborative approach to the analysis representing professional and PPI perspectives aims to enhance researcher reflexivity, and hence quality of the analysis[42].

The same format will be used for 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

Insight into patient experiences associated with discectomy surgery will provide valuable data to inform clinical practice. Barriers and facilitators affecting current outcomes and strategies patients utilise to manage and cope with persistent post-op problems will also be better understood. Analysis of study results will inform precision rehabilitation to enhance 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[43]. 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 University of Birmingham and Queen Elizabeth Hospital Birmingham 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 (PPI)

The patient perspective is central to this study with recognition of the growing understanding of the value of patient representation[44]. 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. One patient representative has been involved with the team for >5years 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 wellbeing 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 wellbeing of the participant. With discussion and consent from the participant, the site clinical team would be notified to ensure an appropriate plan 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-personalized. 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.

PEER REVIEW.

A parallel study protocol[36] has undergone 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 (MDBP) which is commissioned by Health Education England (HEE)/ West Midlands. The programme is hosted by the National Institute for Health research (NIHR)/ Wellcome Trust Clinical Research Facility at the University Hospitals Birmingham NHS Foundation Trust.

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AUTHOR CONTRIBUTIONS

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

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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.

COMPETING INTERESTS STATEMENT

None declared

DATA STATEMENT

No further data are available.

ROVENANCE AND PEER REVIEW

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

REFERENCES

1 NICE guideline NG59 Low Back Pain and Sciatica in over 16s: Assessment and Management. November 2016

2 National Low Back and radicular Pain Pathway; (2017) Trauma Programme of Care: NHS England http://www.ukssb.com/assets/PDFs/2017/August/National-Low-Back-and-Radicular-Pain-Pathway-2017_final_June_2017.pdf

3 Gibson A, Waddell G. Surgical Interventions for lumbar disc prolapse. *Cochrane Database of Systematic reviews* 2007doi:10.1002/14651858.CD001350.pub4

4 Hospital Episode Statistics (HES); accessed 27/4/18 https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2016-17

5 Parker SL, Xu R, McGirt MJ, et al. Long-term back pain after a single level discectomy for radiculopathy: incidence and health care cost analysis. *J Neurosurg Spine* 2010;12:178-82

6 Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: The Spine Patient Outcomes Research Trial (SPORT) observational cohort. *J Am Med Assoc* 2006;296(20):2451-2459 doi:10.

7 Sherman J, Cauthen J, Schoenberg D, et al. Economic impact of improving outcomes of lumbar discectomy. *Spine J* 2010;10:108–16.

8 Werner DAT, Grotle M, Gulati S, et al. Criteria for failure and worsening after surgery for lumbar disc herniation: a multicenter observational study based on data from the Norwegian Registry for Spine Surgery. *Eur Spine J* 2017;26(10):2650–9.

9 Machado GC, Witzleb A J, Fritsch C, et al. Patients with Sciatica still experience pain and disability 5 years after surgery: A systematic review with meta-analysis of cohort studies. *European journal of Pain* 2016; 20(10):1700-1709

10 Arts MP, Brand R, van den Akker ME, et al. The Hague Spine Intervention Prognostic Study Group (SIPS). Tubular diskectomy vs conventional microdiskectomy for sciatica: a randomised controlled trial. *JAMA*. 2009;302:149–158.

11 Peul WC, van Houwelingen HC, van den Hout WB, et al. Surgery versus Prolonged Conservative treatment for Sciatica. *N EngJ Med* 2007;356:2245-2256 https://doi:10.1056/NEJMoa064039

12 Yee A, Adjei N, Do J, et al. Do patient expectations of spinal surgery relate to functional outcome? *Clinical Orthopaedics and Related Research* 2008;*466*(5):1154–1161. https://doi.org/10.1007/s11999-008-0194-7

13 Elkan P, Lagerbäck T, Möller H, et al. Response rate does not affect patient-reported outcome after lumbar discectomy. *European Spine Journal*, 2018;1–9. https://doi.org/10.1007/s00586-018-5541-0

14 Solberg TK, Nygaard OP, Sjaavik K, et al. The risk of "getting worse" after lumbar microdiscectomy. *Eur Spine J* 2005; 14(1):49-54. https://doi10.1007/s00586-004-0721-5.

15 Fritzell, P, Knutsson B, Sanden B, et al. Recurrent versus primary lumbar disc herniation surgery: patient -reported outcomes in the Swedish Spine Register Swespine *Clinical Orthopaedics and Related Research*, 2015 Vol.473(6)1978-1984.

16 Drazin, D, Ugiliweneza B, Al-khouja L et al. Treatment of recurrent disc herniation: A Systematic review. *Cureus* 8(5) e622. https://doi 10.7759/cureus.622

17 Den Boer J, Oostendorp R, Beems t, et al. A systematic review of bio-psychosocial risk factors for an unfavourable outcome after lumbar disc surgery. *Eur Spine* 2006;15(5):527-536.

18 Wilson CA, Roffey D M, Chow D, et al. A systematic review of preoperative predictors for postoperative clinical outcomes following lumbar discectomy. *Spine Journal*. Elsevier Inc. https://doi.org/10.1016/j.spinee.2016.08.003

19 McGregor AH, Dicken B, Jamrozik K: National audit of post-operative management in spine surgery. *BMC Musculoskeletal Disorders* 2006;7:47

20 Williamson E, White L, Rushton A. A survey of post-operative management for patients following first time lumbar discectomy. *Eur Spine Journal* 2007;16(6):795-802

21 Oosterhuis T, Costa LOP, Maher CG, et al. Rehabilitation after lumbar disc surgery. *Cochrane Database of Systematic Reviews* 2014, Issue 3. Art. No.: CD003007. https://doi: 10.1002/14651858.CD003007.pub3.

22 Rushton A, Wright C, Goodwin P, et al. Physiotherapy Rehabilitation Post First Lumbar Discectomy. *Spine*, 2011; *36*(14):E961–E972 https://doi.org/10.1097/BRS.0b013e3181f0e8f8

23 Buchbinder R, Van Tulden M, Oberg B, et al. Low Back Pain: a call for action. *The Lancet* 2018 March p1-5 DOI:10.1016/S0140-6736(18)30488-

24 Yorimitsu E, Chiba K, Toyama Y, et al. Long -term outcomes of standard discectomy for lumbar disc herniation: a follow-up study of more than 10 years. *Spine* 2001;26(6):652-657

25 Caragee EJ, Helms E, O'Sullivan GS. Are post-operative activity restrictions necessary after posterior lumbar discectomy? A prospective study of outcomes in 50 consecutive cases. *Spine* 1996; 21:1893-7.

26 Carragee EJ, Han MY, Yang B, et al. Activity restrictions after posterior lumbar discectomy. A prospective study of outcomes in 152 cases with no postoperative restrictions. *Spine.* 1999: 24: 2346-51.

27 Bono CM, Leonard DA, Cha TD, et al. The effect of short (2-week) versus long (6-week) post-operative restrictions following discectomy: a prospective randomised control trial. *Eur Spine Journal* 2017 Vol 26(3):905-912.

28 Daly C, Lim KZ, Lewis J, et al. Lumbar microdiscectomy and post-operative activity restrictions: a protocol for a single blinded randomised controlled trial. *BMC Musculoskeletal Disorders* 2017 18:312 https://doi:10.1186/s12891-017-1681-3

29 Hersht M, Massicotte EM, Bernstein M. Patient satisfaction with outpatient lumbar microsurgical discectomy: a qualitative study. *Can J Surg* 2007;50:445

30 Davis R E, Vincent C, Henley A, McGregor A. Exploring the care experience of patients undergoing spinal surgery: A qualitative study. *Journal of Evaluation in Clinical Practice* 2013;*19*(1) 132–138. https://doi.org/10.1111/j.1365-2753.2011.01783.x

31 Rushton A, Heneghan N, Heap A, et al. Patient and physiotherapist perceptions of rehabilitation following primary lumbar discectomy: a qualitative focus group study embedded within an external pilot and feasibility trial. *BMJ Open*, 2017; 7:e015878. https://doi:10.1136/bmjopen-2017-015878

32 Williamson J, Bulley C, Coutts F. What do patients feel they can do following lumbar microdiscectomy? A qualitative study. *Disabil Rehabil* 2008;30:1367–73 https://doi: 10.1080/09638280701639915

33 Smith JE, Osborn M. Interpretative phenomenological analysis. In JA Smith (ed) Qualitative Psychology: A Practical Guide to Methods. London: Sage (2nd ed); 2008.

34 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal of Quality in Health Care* 2007; 19(6):349-357 https://doi:10.1093/intphc/mzm042

35 Ostelo RW, Costa L O, Maher C G, et al. Rehabilitation after lumbar disc surgery. *Cochrane Database of Systematic Reviews* 2008;(4):CD003007. https://doi.org/10.1002/14651858.CD003007.pub2

36 Rushton A, Staal JB, Verra M, et al. Patient jounrey following lumbar spinal fusion surgery (LSFS): protocol for a multicentre qualitative analysis of the patient rehabilitation experience (FuJourn). *BMJ Open* 2018; 8;e020710 https://doi:10.1136/bmjopen-2017-020710

37 Dale O, Hagen KB. Despite technical problems personal digital assistants outperform pen and paper when collecting patient diary data. *Journal of Clinical Epidemiology*. 2007 60(1):8-17.

38 Willems P et al. Clinical decision making in spinal fusion for chronic low back pain. *BMJ Open* 2011;1:e000391.

39 Brocki J, Wearden A . A critical evaluation of the use of interpretative phenomenological analysis (IPA) in health psychology. *Psychology and Health;*2006 21(1):87-108.

40 Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field methods*. 2006;18(1):59-82

41 Biggerstaff D, Thompson AR. Interpretative phenomenological Analysis (IPA): A Qualitative Methodology of Choice in Healthcare Research. *Qualitative Research in Psychology* 2008;5:214-224

42 Rodham K, Fox F, Doran N. Exploring analytical trustworthiness and the process of reaching consensus in interpretative phenomenological analysis: lost in transcription. *International Journal of Social Research Methodology* 2015;18(1):59-71

43 Department of health and social care. NHS Framework 2013-2014; Nov 2012 https://www.gov.uk/government/publications/nhs-outcomes-framework-2013-to-2014

44 Garfield S, Jheeta S, Husson F, et al. Lay involvement in the analysis of qualitative data in health services research: a descriptive study. *Research Involvement and Engagement* 2016:2(29) https://doi10:1186/s40900-016-0041-z

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The patient journey following lumbar discectomy surgery: protocol for a single centre qualitative analysis of the patient experience (DiscJourn)

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TITLE

The 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% patients report sub-optimal functional recovery and quality of life. The impact and meaning of the surgical experience from the patients' perspective is not fully understood. Furthermore, there is limited evidence guiding post-operative management with significant clinical practice variation and it is unclear if current post-operative support is valued, beneficial or meets patients' needs and expectations. This study aims to address the evidence gap by moving beyond current knowledge to capture 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 post-surgery discharge. A topic guide, developed from literature and our previous work with input from two patient co-investigators, will guide interviews with flexibility to explore interesting or participant 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 one year post-surgery 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). The study conclusions will be disseminated through conferences and peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This qualitative study offers unique in-depth understanding of the patient journey capturing 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 post-operative 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 post-lumbar discectomy evidence base.
-

INTRODUCTION

Lumbardiscectomy is the most common spinal surgical procedure in the UK[1] and 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 to 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 surgery itself, post-operative 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 post-surgery year to inform practice changes towards 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 surgery[12] 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 post-surgery[9] and 4% of patients described post-surgery worsening[14]. Persistent motor deficit, lower quality of life scores[8], and recurrent disc protrusions requiring revision surgery[15,16] have also been documented with an array of biopsychosocial factors (including pain severity, 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. One study focused on perceptions of outpatient surgery[19] and another investigated what patients felt they could do post-surgery[20]. A further focus group study involved retrospective recall of experiences 1 year post-surgery (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 post-surgery 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 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 post-surgery demonstrating potential to improve pain and disability[28], movement and physical impairment[29] in the short term. Furthermore it remains unclear if *all* patients require intensive post-discectomy rehabilitation.

Evidence also highlights variation in post-discectomy management (including referral to physiotherapy content, advice and guidance offered)[10,30 31] and survey results[31] showed lack of consistency in post-operative advice with restricted activities including sitting, lifting, return to

work, driving advocated for a variety of post-operative periods. Several studies also challenge the need for post-lumbar 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' post-operative experiences providing insight into rehabilitation content and perceived post-discectomy 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 disability[36] with exposure to healthcare sometimes producing harmful effects. A long term post-discectomy analysis[37] found that only 40% of patients continued recreational activities, including sports, undertaken pre-surgery.

Another qualitative investigation[20] undertook semi-structured interviews, finding high levels of post-operative anxiety related to restricted post-operative movement and sub-optimal recovery, and that physiotherapists did not help participants fully explore their potential for activity. The influence of health care providers within post-discectomy management is not fully understood.

This study is the first to undertake patient interviews and track patients throughout the first post-discectomy 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" 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 post-discectomy needs as identified by the individual patient themselves.

Aim

To gain understanding of patients' perceptions and capture 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 lifestyle including exploration of barriers and facilitators.

3. To explore the patient's perspective regarding the stages/ components of the discectomy journey.

4. To explore similarities and differences between patients/ patient groups (e.g. emergency versus elective surgery).

5. To explore patient perceived post-surgery 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.

6. 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 experience (PPIE) 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 post-discectomy care, satisfaction and outcomes.

METHODS AND ANALYSIS:

Theoretical framework

A phenomenology framework using Interpretive Phenomenological Analysis (IPA) was selected to explore patients' experience of the lumbar discectomy journey.. This framework enables exploration the experience of the surgery and post-operative 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 generalisability[38p2-5].

Study design

Qualitative research employing IPA[38] 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 is it like to "stand in the participant's shoes". IPA is therefore a dynamic process with interpretative activities making meaning (participant's account) and making sense (researcher decoding) of an experience from the patients' perspective i.e. a combination of description and interpretation.

IPA is also idiographic, meaning that single cases will be analysed in-depth and individual experiences 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 base[38,p51].

Study Setting

One secondary care setting (Queen Elizabeth Hospital, Birmingham NHS Trust (QEHB)) 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 post-operative period following discharge home 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 post-surgery appointments to avoid additional journeys.

Following informed consent, interviews will be conducted by the 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, clinical uniform will not be worn during the interviews. Based on previous experience, it is predicted that interview duration will be approximately 60 minutes. 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 2 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 pre- and post-operative 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 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 endevour to create a relaxed and comfortable environmentand for example, will engage the participant in general conversation. This will also enable the interviewer to check the participants' wellbeing. 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 though transcriptions and add any further comments or reflections. Dependent on a participant's preference, this process will be undertaken by post or email with discussion regarding content also offered using telephone or Skype.

12-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 (e.g. 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 findings from our recent post lumbar 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 capture 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" [38p218] As required for IPA design, participants will represent a homogenous population relating to the topic of investigation[38] i.e. 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, gender[42] and other factors identified as influencing lumbar disc surgery outcomes (including level of education, pre-operative pain level, work satisfaction, sick leave duration from work, co-existing psychological issues, coping strategies)[17-18].

The IPA method involves a joint process between the patient and 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 i.e. 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 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. 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 (e.g. 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 pre or post operatively- 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 experience[45] and is suited to health care 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 pre-suppositions[45]. However, to ensure rigor of analysis, 4 stages will be undertaken:

Stage 1: Interviews will be transcribed verbatim and will include detail of non-verbal content (e.g. speech dynamics[45]). The PI (LW) will review the transcribed text and audio recordings with field notes.

Stage 2: Preliminary themes will be identified and presented firstly to investigator AM (conducting data analysis parallel study[40]) 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 6 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 (LW) 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. Halkier[46] describes 3 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. 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 3 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 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

Whilst 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 post-discectomy year. Exposing experiences, perceptions, beliefs and considering the content and value of therapeutic interventions, will shape changes to post-lumbar discectomy care based on patient perceived needs. Valuable understanding of barriers and facilitators affecting outcomes and strategies patients' utilise to manage and cope with persistent post-op 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 University of Birmingham and Queen Elizabeth Hospital Birmingham 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 (PPI)

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 >5years 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 wellbeing 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 wellbeing of the participant. With discussion and consent from the participant, the site clinical team would be notified to ensure an appropriate plan 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-personalized. 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 review journals with presentation at appropriate international conferences.

PEER REVIEW

A parallel study protocol[40] has undergone 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 (MDBP) which is commissioned by Health Education England (HEE)/ West Midlands. The programme is hosted by the National Institute for Health research (NIHR)/ Wellcome Trust Clinical Research Facility at the University Hospitals Birmingham NHS Foundation Trust.

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AUTHORS' CONTRIBUTIONS:

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

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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.

COMPETING INTERESTS STATEMENT.

None declared

PROVENANCE AND PEER REVIEW

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

REFERENCES.

1 Hospital Episode Statistics (HES); accessed 27/4/18 https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2016-17

2 Parker SL, Xu R, McGirt MJ, et al. Long-term back pain after a single level discectomy for radiculopathy: incidence and health care cost analysis. *J Neurosurg Spine* 2010;12:178-82

3 Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: The Spine Patient Outcomes Research Trial (SPORT) observational cohort. *J Am Med Assoc* 2006;296(20):2451-2459 doi:10.

4 Sherman J, Cauthen J, Schoenberg D, et al. Economic impact of improving outcomes of lumbar discectomy. *Spine J* 2010;10:108–16.

5 Gibson A, Waddell G. Surgical Interventions for lumbar disc prolapse. *Cochrane Database of Systematic reviews* 2007doi:10.1002/14651858.CD001350.pub4

6 NICE guideline NG59 Low Back Pain and Sciatica in over 16s: Assessment and Management. November 2016

7 National Low Back and radicular Pain Pathway; (2017) Trauma Programme of Care: NHS England http://www.ukssb.com/assets/PDFs/2017/August/National-Low-Back-and-Radicular-Pain-Pathway-2017_final_June_2017.pdf

8 Werner DAT, Grotle M, Gulati S, et al. Criteria for failure and worsening after surgery for lumbar disc herniation: a multicenter observational study based on data from the Norwegian Registry for Spine Surgery. *Eur Spine J* 2017;26(10):2650–9.

9 Machado GC, Witzleb A J, Fritsch C, et al. Patients with Sciatica still experience pain and disability 5 years after surgery: A systematic review with meta-analysis of cohort studies. *European journal of Pain* 2016; 20(10):1700-1709

10 Arts MP, Brand R, van den Akker ME, et al. The Hague Spine Intervention Prognostic Study Group (SIPS). Tubular diskectomy vs conventional microdiskectomy for sciatica: a randomised controlled trial. *JAMA*. 2009;302:149–158.

11 Peul WC, van Houwelingen HC, van den Hout WB, et al. Surgery versus Prolonged Conservative treatment for Sciatica. *N EngJ Med* 2007;356:2245-2256 https://doi:10.1056/NEJMoa064039

12 Yee A, Adjei N, Do J, et al. Do patient expectations of spinal surgery relate to functional outcome? *Clinical Orthopaedics and Related Research* 2008;*466*(5):1154–1161. https://doi.org/10.1007/s11999-008-0194-7

13 Elkan P, Lagerbäck T, Möller H, et al. Response rate does not affect patient-reported outcome after lumbar discectomy. *European Spine Journal*, 2018;1–9. https://doi.org/10.1007/s00586-018-5541-0

14 Solberg TK, Nygaard OP, Sjaavik K, et al. The risk of "getting worse" after lumbar microdiscectomy. *Eur Spine J* 2005; 14(1):49-54. https://doi10.1007/s00586-004-0721-5.

15 Fritzell, P, Knutsson B, Sanden B, et al. Recurrent versus primary lumbar disc herniation surgery: patient -reported outcomes in the Swedish Spine Register Swespine *Clinical Orthopaedics and Related Research*, 2015 Vol.473(6)1978-1984.

16 Drazin, D, Ugiliweneza B, Al-khouja L et al. Treatment of recurrent disc herniation: A Systematic review. *Cureus* 8(5) e622. https://doi 10.7759/cureus.622

17 Den Boer J, Oostendorp R, Beems t, et al. A systematic review of bio-psychosocial risk factors for an unfavourable outcome after lumbar disc surgery. *Eur Spine* 2006;15(5):527-536.

18 Wilson CA, Roffey D M, Chow D, et al. A systematic review of preoperative predictors for postoperative clinical outcomes following lumbar discectomy. *Spine Journal*. Elsevier Inc. https://doi.org/10.1016/j.spinee.2016.08.003

19Hersht M, Massicotte EM, Bernstein M. Patient satisfaction with outpatient lumbar microsurgical discectomy: a qualitative study. *Can J Surg* 2007;50:445

20Williamson J, Bulley C, Coutts F. What do patients feel they can do following lumbar microdiscectomy? A qualitative study. *Disabil Rehabil* 2008;30:1367–73 https://doi: 10.1080/09638280701639915

21 Davis R E, Vincent C, Henley A, McGregor A. Exploring the care experience of patients undergoing spinal surgery: A qualitative study. *Journal of Evaluation in Clinical Practice* 2013;*19*(1)132–138. https://doi.org/10.1111/j.1365-2753.2011.01783.x

22 Rushton A, Heneghan N, Heap A, et al. Patient and physiotherapist perceptions of rehabilitation following primary lumbar discectomy: a qualitative focus group study embedded within an external pilot and feasibility trial. *BMJ Open*, 2017; 7:e015878. https://doi:10.1136/bmjopen-2017-015878

23 Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open*;3(1)1-18 doi:10.1136/bmjopen2012-001570

24 Department of Health. High Quality care for all: NHS next stage review final report 2008 ISBN9780101743228

25 Tutton E, Achten J, Lamb SE, Willett K, Costa ML. A qualitative study of patient experience of an open fracture of the lower limb during acute care. *Bone Joint Journal*, 2018;100-8,522-526.

26 Osborn M, Smith JA. The personal experience of chronic benign lower back pain: An interpretative phenomenological analysis. *British Journal of Health Psychology* 1998:3(1)65-83 https://doi.org/10.1111/j.2044-8287.1998.tb00556.x

27 Dawson C, Adams J, Fenlon D. The experiences of people who receive swallow therapy following surgical treatment of head and neck cancer. *Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology*. https://doi.org.10.1016/j.000.2019.03.012

28 Oosterhuis T, Costa LOP, Maher CG, et al. Rehabilitation after lumbar disc surgery. *Cochrane Database of Systematic Reviews* 2014, Issue 3. Art. No.: CD003007. https://doi: 10.1002/14651858.CD003007.pub3.

29Rushton A, Wright C, Goodwin P, et al. Physiotherapy Rehabilitation Post First Lumbar Discectomy. *Spine*, 2011; *36*(14):E961–E972 https://doi.org/10.1097/BRS.0b013e3181f0e8f8

30 McGregor AH, Dicken B, Jamrozik K: National audit of post-operative management in spine surgery. *BMC Musculoskeletal Disorders* 2006;7:47

31 Williamson E, White L, Rushton A. A survey of post-operative management for patients following first time lumbar discectomy. *Eur Spine Journal* 2007;16(6):795-802

32 Caragee EJ, Helms E, O'Sullivan GS. Are post-operative activity restrictions necessary after posterior lumbar discectomy? A prospective study of outcomes in 50 consecutive cases. *Spine* 1996; 21:1893-7.

33 Carragee EJ, Han MY, Yang B, et al. Activity restrictions after posterior lumbar discectomy. A prospective study of outcomes in 152 cases with no postoperative restrictions. *Spine.* 1999: 24: 2346-51.

34Bono CM, Leonard DA, Cha TD, et al. The effect of short (2-week) versus long (6-week) post-operative restrictions following discectomy: a prospective randomised control trial. *Eur Spine Journal* 2017 Vol 26(3):905-912.

35 Daly C, Lim KZ, Lewis J, et al. Lumbar microdiscectomy and post-operative activity restrictions: a protocol for a single blinded randomised controlled trial. *BMC Musculoskeletal Disorders* 2017 18:312 https://doi:10.1186/s12891-017-1681-3

36Buchbinder R, Van Tulden M, Oberg B, et al. Low Back Pain: a call for action. *The Lancet* 2018 March p1-5 DOI:10.1016/S0140-6736(18)30488-

37 Yorimitsu E, Chiba K, Toyama Y, et al. Long -term outcomes of standard discectomy for lumbar disc herniation: a follow-up study of more than 10 years. *Spine* 2001;26(6):652-657

38Smith JE, Osborn M. Interpretative phenomenological analysis. In JA Smith (ed) Qualitative Psychology: A Practical Guide to Methods. London: Sage (2nd ed); 2008.

39Ostelo RW, Costa L O, Maher C G, et al. Rehabilitation after lumbar disc surgery. *Cochrane Database of Systematic Reviews* 2008;(4):CD003007. https://doi.org/10.1002/14651858.CD003007.pub2

40Rushton A, Staal JB, Verra M, et al. Patient jounrey following lumbar spinal fusion surgery (LSFS): protocol for a multicentre qualitative analysis of the patient rehabilitation experience (FuJourn). *BMJ Open* 2018; 8;e020710 https://doi:10.1136/bmjopen-2017-020710

41Dale O, Hagen KB. Despite technical problems personal digital assistants outperform pen and paper when collecting patient diary data. *Journal of Clinical Epidemiology*. 2007 60(1):8-17.

42Willems P et al. Clinical decision making in spinal fusion for chronic low back pain. *BMJ Open* 2011;1:e000391.

43Brocki J, Wearden A . A critical evaluation of the use of interpretative phenomenological analysis (IPA) in health psychology. *Psychology and Health;*2006 21(1):87-108.

44Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field methods*. 2006;18(1):59-82

45 Biggerstaff D, Thompson AR. Interpretative phenomenological Analysis (IPA): A Qualitative Methodology of Choice in Healthcare Research. *Qualitative Research in Psychology* 2008;5:214-224

46 Halkier B, Methodological Practicalities in Analytical Generalization. *Qualitative Inquiry* 2011:17(9)787-797 https://doi.org/10.1177/1077800411423194

47 Rodham K, Fox F, Doran N. Exploring analytical trustworthiness and the process of reaching consensus in interpretative phenomenological analysis: lost in transcription. *International Journal of Social Research Methodology* 2015;18(1):59-71

48Department of health and social care. NHS Framework 2013-2014; Nov 2012 https://www.gov.uk/government/publications/nhs-outcomes-framework-2013-to-2014

49Garfield S, Jheeta S, Husson F, et al. Lay involvement in the analysis of qualitative data in health services research: a descriptive study. *Research Involvement and Engagement* 2016:2(29) https://doi10:1186/s40900-016-0041-z

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

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TITLE

The 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% patients report sub-optimal functional recovery and quality of life. The impact and meaning of the surgical experience from the patients' perspective is not fully understood. Furthermore, there is limited evidence guiding post-operative management with significant clinical practice variation and it is unclear if current post-operative 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 post-surgery discharge. A topic guide, developed from literature and our previous work with input from two patient co-investigators, will guide interviews with flexibility to explore interesting or participant 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 one year post-surgery 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 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 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 post-operative 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 post-lumbar discectomy evidence base.

INTRODUCTION

Lumbar discectomy is the most common spinal surgical procedure in the UK[1] and 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 to 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 surgery itself, post-operative 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 post-surgery year to inform practice changes towards 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 surgery[12] 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 post-surgery[9] and 4% of patients described post-surgery worsening[14]. Persistent motor deficit, lower quality of life scores[8], and recurrent disc protrusions requiring revision surgery[15,16] have also been documented with an array of biopsychosocial factors (including pain severity, 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 surgery[19] and another investigated what patients felt they could do post-surgery[20]. A further focus group study involved retrospective recall of experiences 1 year post-surgery (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 post-surgery 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 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 post-surgery demonstrating potential to improve pain and disability[28], movement and physical impairment[29] in the short term. Furthermore it remains unclear if *all* patients require intensive post-discectomy rehabilitation.

Evidence also highlights variation in post-discectomy management (including referral to physiotherapy content, advice and guidance offered)[10,30 31] and survey results[31] showed lack

of consistency in post-operative advice with restricted activities including sitting, lifting, return to work, driving advocated for a variety of post-operative periods. Several studies also challenge the need for post-lumbar 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' post-operative experiences providing insight into rehabilitation content and perceived post-discectomy 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 disability[36] with exposure to healthcare sometimes producing harmful effects. A long term post-discectomy analysis[37] found that only 40% of patients continued recreational activities, including sports, undertaken pre-surgery.

Another qualitative investigation[20] undertook semi-structured interviews, finding high levels of post-operative anxiety related to restricted post-operative movement and sub-optimal recovery, and that physiotherapists did not help participants fully explore their potential for activity. The influence of health care providers within post-discectomy management is not fully understood.

To our knowledge, this study is the first to undertake patient interviews and track patients throughout the first post-discectomy 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 (i.e. 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 post-discectomy 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 (e.g. emergency versus elective surgery).

6. To explore patient perceived post-surgery 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 experience (PPIE) 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 post-discectomy care, satisfaction and outcomes.

METHODS AND ANALYSIS:

Theoretical framework

A phenomenology framework using Interpretive Phenomenological Analysis (IPA) was selected to explore patients' experience of the lumbar discectomy journey. This framework enables exploration the experience of the surgery and post-operative 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 generalisability[38p2-5].

Study design

Qualitative research employing IPA[38] 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 making sense (researcher decoding) of an experience from the patients' perspective i.e. a combination of description and interpretation.

IPA is also idiographic, meaning that single cases will be analysed in-depth and individual experiences 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 base[38,p51].

Study Setting

One secondary care setting (Queen Elizabeth Hospital, Birmingham NHS Trust (QEHB)) 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 post-operative period following discharge home (1-3 weeks post-surgery) 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 post-surgery appointments to avoid additional journeys.

Following informed consent, interviews will be conducted by the 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, clinical uniform will not be worn during the interviews. Based on previous experience, it is predicted that interview duration will be approximately 60 minutes. 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 2 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 pre- and post-operative 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 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 endevour to create a relaxed and comfortable environmentand for example, will engage the participant in general conversation. This will also enable the interviewer to check the participants' wellbeing. 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 though transcriptions and add any further comments or reflections. Dependent on a participant's preference, this process will be undertaken by post or email with discussion regarding content also offered using telephone or Skype.

12-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 (e.g. 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 findings from our recent post lumbar 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" [38p218] As required for IPA design, participants will represent a homogenous population relating to the topic of investigation[38] i.e. 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, gender[42] and other factors identified as influencing lumbar disc surgery outcomes (including level of education, pre-operative pain level, work satisfaction, sick leave duration from work, co-existing psychological issues, coping strategies)[17-18].

The IPA method involves a joint process between the patient and 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 i.e. 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 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. 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 (e.g. 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 pre or post operatively- 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 experience[45] and is suited to health care 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 pre-suppositions[45]. However, to ensure rigor of analysis, 4 stages will be undertaken:

Stage 1: Interviews will be transcribed verbatim and will include detail of non-verbal content (e.g. speech dynamics[45]). The PI (LW) will review the transcribed text and audio recordings with field notes.

Stage 2: Preliminary themes will be identified and presented firstly to investigator AM (conducting data analysis parallel study[40]) 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 6 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 (LW) 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. Halkier[46] describes 3 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. 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 3 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 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

Whilst 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 post-discectomy year. Exposing experiences, perceptions, beliefs and considering the content and value of therapeutic interventions, will shape changes to post-lumbar discectomy care based on patient perceived needs. Valuable understanding of barriers and facilitators affecting outcomes and strategies patients' utilise to manage and cope with persistent post-op 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 University of Birmingham and Queen Elizabeth Hospital Birmingham 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 (PPI)

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 >5years 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 wellbeing 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 wellbeing of the participant. With discussion and consent from the participant, the site clinical team would be notified to ensure an appropriate plan 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-personalized. 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 review journals with presentation at appropriate international conferences.

PEER REVIEW

A parallel study protocol[40] has undergone 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 (MDBP) which is commissioned by Health Education England (HEE)/ West Midlands. The programme is hosted by the National Institute for Health research (NIHR)/ Wellcome Trust Clinical Research Facility at the University Hospitals Birmingham NHS Foundation Trust.

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AUTHORS' CONTRIBUTIONS:

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

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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.

COMPETING INTERESTS STATEMENT.

None declared

PROVENANCE AND PEER REVIEW

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

REFERENCES.

1 Hospital Episode Statistics (HES); accessed 27/4/18 https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2016-17

2 Parker SL, Xu R, McGirt MJ, et al. Long-term back pain after a single level discectomy for radiculopathy: incidence and health care cost analysis. *J Neurosurg Spine* 2010;12:178-82

3 Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical vs nonoperative treatment for lumbar disk herniation: The Spine Patient Outcomes Research Trial (SPORT) observational cohort. *J Am Med Assoc* 2006;296(20):2451-2459 doi:10.

4 Sherman J, Cauthen J, Schoenberg D, et al. Economic impact of improving outcomes of lumbar discectomy. *Spine J* 2010;10:108–16.

5 Gibson A, Waddell G. Surgical Interventions for lumbar disc prolapse. *Cochrane Database of Systematic reviews* 2007doi:10.1002/14651858.CD001350.pub4

6 NICE guideline NG59 Low Back Pain and Sciatica in over 16s: Assessment and Management. November 2016

7 National Low Back and radicular Pain Pathway; (2017) Trauma Programme of Care: NHS England http://www.ukssb.com/assets/PDFs/2017/August/National-Low-Back-and-Radicular-Pain-Pathway-2017_final_June_2017.pdf

8 Werner DAT, Grotle M, Gulati S, et al. Criteria for failure and worsening after surgery for lumbar disc herniation: a multicenter observational study based on data from the Norwegian Registry for Spine Surgery. *Eur Spine J* 2017;26(10):2650–9.

9 Machado GC, Witzleb A J, Fritsch C, et al. Patients with Sciatica still experience pain and disability 5 years after surgery: A systematic review with meta-analysis of cohort studies. *European journal of Pain* 2016; 20(10):1700-1709

10 Arts MP, Brand R, van den Akker ME, et al. The Hague Spine Intervention Prognostic Study Group (SIPS). Tubular diskectomy vs conventional microdiskectomy for sciatica: a randomised controlled trial. *JAMA*. 2009;302:149–158.

11 Peul WC, van Houwelingen HC, van den Hout WB, et al. Surgery versus Prolonged Conservative treatment for Sciatica. *N EngJ Med* 2007;356:2245-2256 https://doi:10.1056/NEJMoa064039

12 Yee A, Adjei N, Do J, et al. Do patient expectations of spinal surgery relate to functional outcome? *Clinical Orthopaedics and Related Research* 2008;*466*(5):1154–1161. https://doi.org/10.1007/s11999-008-0194-7

13 Elkan P, Lagerbäck T, Möller H, et al. Response rate does not affect patient-reported outcome after lumbar discectomy. *European Spine Journal*, 2018;1–9. https://doi.org/10.1007/s00586-018-5541-0

14 Solberg TK, Nygaard OP, Sjaavik K, et al. The risk of "getting worse" after lumbar microdiscectomy. *Eur Spine J* 2005; 14(1):49-54. https://doi10.1007/s00586-004-0721-5.

15 Fritzell, P, Knutsson B, Sanden B, et al. Recurrent versus primary lumbar disc herniation surgery: patient -reported outcomes in the Swedish Spine Register Swespine *Clinical Orthopaedics and Related Research*, 2015 Vol.473(6)1978-1984.

16 Drazin, D, Ugiliweneza B, Al-khouja L et al. Treatment of recurrent disc herniation: A Systematic review. *Cureus* 8(5) e622. https://doi 10.7759/cureus.622

17 Den Boer J, Oostendorp R, Beems t, et al. A systematic review of bio-psychosocial risk factors for an unfavourable outcome after lumbar disc surgery. *Eur Spine* 2006;15(5):527-536.

18 Wilson CA, Roffey D M, Chow D, et al. A systematic review of preoperative predictors for postoperative clinical outcomes following lumbar discectomy. *Spine Journal*. Elsevier Inc. https://doi.org/10.1016/j.spinee.2016.08.003

19Hersht M, Massicotte EM, Bernstein M. Patient satisfaction with outpatient lumbar microsurgical discectomy: a qualitative study. *Can J Surg* 2007;50:445

20Williamson J, Bulley C, Coutts F. What do patients feel they can do following lumbar microdiscectomy? A qualitative study. *Disabil Rehabil* 2008;30:1367–73 https://doi: 10.1080/09638280701639915

21 Davis R E, Vincent C, Henley A, McGregor A. Exploring the care experience of patients undergoing spinal surgery: A qualitative study. *Journal of Evaluation in Clinical Practice* 2013;*19*(1)132–138. https://doi.org/10.1111/j.1365-2753.2011.01783.x

22 Rushton A, Heneghan N, Heap A, et al. Patient and physiotherapist perceptions of rehabilitation following primary lumbar discectomy: a qualitative focus group study embedded within an external pilot and feasibility trial. *BMJ Open*, 2017; 7:e015878. https://doi:10.1136/bmjopen-2017-015878

23 Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open*;3(1)1-18 doi:10.1136/bmjopen2012-001570

24 Department of Health. High Quality care for all: NHS next stage review final report 2008 ISBN9780101743228

25 Tutton E, Achten J, Lamb SE, Willett K, Costa ML. A qualitative study of patient experience of an open fracture of the lower limb during acute care. *Bone Joint Journal*, 2018;100-8,522-526.

26 Osborn M, Smith JA. The personal experience of chronic benign lower back pain: An interpretative phenomenological analysis. *British Journal of Health Psychology* 1998:3(1)65-83 https://doi.org/10.1111/j.2044-8287.1998.tb00556.x

27 Dawson C, Adams J, Fenlon D. The experiences of people who receive swallow therapy following surgical treatment of head and neck cancer. *Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology*. https://doi.org.10.1016/j.000.2019.03.012

28 Oosterhuis T, Costa LOP, Maher CG, et al. Rehabilitation after lumbar disc surgery. *Cochrane Database of Systematic Reviews* 2014, Issue 3. Art. No.: CD003007. https://doi: 10.1002/14651858.CD003007.pub3.

29Rushton A, Wright C, Goodwin P, et al. Physiotherapy Rehabilitation Post First Lumbar Discectomy. *Spine*, 2011; *36*(14):E961–E972 https://doi.org/10.1097/BRS.0b013e3181f0e8f8

30 McGregor AH, Dicken B, Jamrozik K: National audit of post-operative management in spine surgery. *BMC Musculoskeletal Disorders* 2006;7:47

31 Williamson E, White L, Rushton A. A survey of post-operative management for patients following first time lumbar discectomy. *Eur Spine Journal* 2007;16(6):795-802

32 Caragee EJ, Helms E, O'Sullivan GS. Are post-operative activity restrictions necessary after posterior lumbar discectomy? A prospective study of outcomes in 50 consecutive cases. *Spine* 1996; 21:1893-7.

33 Carragee EJ, Han MY, Yang B, et al. Activity restrictions after posterior lumbar discectomy. A prospective study of outcomes in 152 cases with no postoperative restrictions. *Spine.* 1999: 24: 2346-51.

34Bono CM, Leonard DA, Cha TD, et al. The effect of short (2-week) versus long (6-week) post-operative restrictions following discectomy: a prospective randomised control trial. *Eur Spine Journal* 2017 Vol 26(3):905-912.

35 Daly C, Lim KZ, Lewis J, et al. Lumbar microdiscectomy and post-operative activity restrictions: a protocol for a single blinded randomised controlled trial. *BMC Musculoskeletal Disorders* 2017 18:312 https://doi:10.1186/s12891-017-1681-3

36Buchbinder R, Van Tulden M, Oberg B, et al. Low Back Pain: a call for action. *The Lancet* 2018 March p1-5 DOI:10.1016/S0140-6736(18)30488-

37 Yorimitsu E, Chiba K, Toyama Y, et al. Long -term outcomes of standard discectomy for lumbar disc herniation: a follow-up study of more than 10 years. *Spine* 2001;26(6):652-657

38Smith JE, Osborn M. Interpretative phenomenological analysis. In JA Smith (ed) Qualitative Psychology: A Practical Guide to Methods. London: Sage (2nd ed); 2008.

39Ostelo RW, Costa L O, Maher C G, et al. Rehabilitation after lumbar disc surgery. *Cochrane Database of Systematic Reviews* 2008;(4):CD003007. https://doi.org/10.1002/14651858.CD003007.pub2

40Rushton A, Staal JB, Verra M, et al. Patient jounrey following lumbar spinal fusion surgery (LSFS): protocol for a multicentre qualitative analysis of the patient rehabilitation experience (FuJourn). *BMJ Open* 2018; 8;e020710 https://doi:10.1136/bmjopen-2017-020710

41Dale O, Hagen KB. Despite technical problems personal digital assistants outperform pen and paper when collecting patient diary data. *Journal of Clinical Epidemiology*. 2007 60(1):8-17.

42Willems P et al. Clinical decision making in spinal fusion for chronic low back pain. *BMJ Open* 2011;1:e000391.

43 Brocki J, Wearden A . A critical evaluation of the use of interpretative phenomenological analysis (IPA) in health psychology. *Psychology and Health;*2006 21(1):87-108.

44 Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field methods*. 2006;18(1):59-82

45 Biggerstaff D, Thompson AR. Interpretative phenomenological Analysis (IPA): A Qualitative Methodology of Choice in Healthcare Research. *Qualitative Research in Psychology* 2008;5:214-224

46 Halkier B, Methodological Practicalities in Analytical Generalization. *Qualitative Inquiry* 2011:17(9)787-797 https://doi.org/10.1177/1077800411423194

47 Rodham K, Fox F, Doran N. Exploring analytical trustworthiness and the process of reaching consensus in interpretative phenomenological analysis: lost in transcription. *International Journal of Social Research Methodology* 2015;18(1):59-71

48 Department of health and social care. NHS Framework 2013-2014; Nov 2012 https://www.gov.uk/government/publications/nhs-outcomes-framework-2013-to-2014

49 Garfield S, Jheeta S, Husson F, et al. Lay involvement in the analysis of qualitative data in health services research: a descriptive study. *Research Involvement and Engagement* 2016:2(29) https://doi10:1186/s40900-016-0041-z