AN INVESTIGATION OF SUBSEQUENT BIRTH AFTER OBSTETRIC ANAL SPHINCTER INJURY.

by

SARA SAMANTHA WEBB

A thesis submitted to the University of Birmingham for the degree of DOCTOR OF PHILOSOPHY

Institute of Applied Health Research
College of Medical & Dental Sciences
The University of Birmingham
May 2017

UNIVERSITY OF
BIRMINGHAM

University of Birmingham Research Archive

e-theses repository

This unpublished thesis/dissertation is copyright of the author and/or third parties. The intellectual property rights of the author or third parties in respect of this work are as defined by The Copyright Designs and Patents Act 1988 or as modified by any successor legislation.

Any use made of information contained in this thesis/dissertation must be in accordance with that legislation and must be properly acknowledged. Further distribution or reproduction in any format is prohibited without the permission of the copyright holder.

ABSTRACT

Obstetric anal sphincter injuries (OASIS) are serious complications of vaginal birth with a reported average worldwide incidence of 4%-6%. They are a recognised major risk factor for anal incontinence resulting in concern amongst women who sustain such injuries when considering the most suitable mode of birth in a subsequent pregnancy.

This thesis contains three studies; a systematic review and meta-analysis of the published literature exploring the impact of a subsequent birth and it's mode on bowel function and/or QoL for women with previous OASIS, a follow-up study on the long-term effects of OASIS on bowel function and QoL and finally a prospective cohort study of women with previous OASIS to assess the impact of subsequent birth and its mode on change in bowel function.

The work in this thesis demonstrated an increase in incidence of bowel symptoms in women with previous OASIS over time and that short-term bowel symptoms were significantly associated with bowel symptoms and QoL. This thesis also showed that the mode of subsequent birth was not significantly associated with bowel symptoms or QoL and for women with previous OASIS who have normal bowel function and no anal sphincter disruption a subsequent vaginal birth is a suitable option.

.

DEDICATION

To Jeremy and Boris.

To Mum and Dad.

ACKNOWLEDGEMENTS

Many thanks to my supervisors Professor Khaled Ismail and Professor Christine MacArthur for their continued support, advice, knowledge, patience and kindness. Alice Sitch for her time and help with the statistical analysis. Matthew Parsons for his support and clinical input. Joanne Hayes for her invaluable assistance with endoanal ultrasonography. The National Institute for Health Research for funding. Professor Khalid Khan and Margarita Manresa for their friendship, support and wisdom. My family for their constant support and belief. Finally, and most importantly, to all of the women who participated in the study and gave their time to improve care for future generations of women.

Table of contents

List of figures 14

List of tables 16

List of abbreviations 22

1 LITERATURE AND CLINICAL PRACTICE REVIEW 23

1.1 Introduction 23

1.1.1 OASIS incidence 24

1.1.2 OASIS risk factors 24

1.1.3 Royal College of Obstetricians and Gynaecologists (RCOG) recommendations for the management of OASIS 28

1.1.4 OASIS classification 29

1.1.5 Method of OASIS repair 32

1.1.6 Recommendations for mode of subsequent birth for women with previous OASIS 32

1.2 Endoanal ultrasound, manometry and image interpretation 34

1.2.1 Anatomy of the anal canal 34

1.2.2 Endoanal Ultrasound 36

1.2.3 Anal manometry 45

1.3 Manchester Health Questionnaire 47

1.4 Specialist OASIS clinics at Birmingham Women's and Children's NHS Foundation Trust 50

1.5 Thesis rationale and overview 52

2 A SYSTEMATIC REVIEW AND META-ANALYSIS OF THE IMPACT OF SUBSEQUENT BIRTH AND ITS MODE FOR WOMEN WITH PREVIOUS OBSTETRIC ANAL SPHINCTER INJURY.➶ 54

2.1 Introduction 54

2.2 Methods 55

2.2.1 Sources 55

2.2.2 Study selection and data extraction 56

2.2.3 Study quality assessment 57

2.2.4 Data synthesis 60

2.3 Results 60

2.3.1 Subsequent birth vs no-subsequent birth (irrespective of mode) for women with previous OASIS – impact on AI. 66

2.3.2 Subsequent birth vs no-subsequent birth (irrespective of mode) for women with previous OASIS – impact on QoL. 74

2.3.3 Subsequent vaginal birth vs subsequent caesarean section for women with previous OASIS – impact on AI. 74

2.3.4 Subsequent vaginal birth vs subsequent caesarean section for women with previous OASIS – impact on QoL..... 76

2.3.5 Sub-analyses with studies using data from women with a subsequent birth after having sustained primary OASIS from 2003 onwards 76

2.4 Discussion 83

2.4.1 Main findings 83

2.4.2 Strengths and Limitations 83

2.4.3 Interpretation of findings 85

2.5 Conclusion 87

2.5.1 Practical recommendations 87

2.5.2 Research recommendations 88

3 LONG-TERM BOWEL FUNCTION AND QUALITY OF LIFE IN WOMEN WHO SUSTAIN OASIS. 89

3.1 Introduction 89

3.2 Aims and objectives 89

3.2.1 Aims 90

3.2.2 Objectives 90

3.3 Study Design 90

3.4 Population 90

3.5 Outcome measures 91

3.6 Data collection 92

3.6.1 Demographics, OASIS characteristics and short-term bowel function data 92

3.6.2 Birth history information, long-term bowel function and QoL data 92

3.7 Data analysis 93

3.7.1 Definition of characteristics 93

3.7.2 Statistical methods 94

3.8 Ethical Approval 95

3.9 Results 96

3.9.1 Baseline characteristics of responders and comparison with non-responders 98

3.9.2 Birth history 102

3.9.3 Recollection of sustaining OASIS 104

3.9.4 Bowel function 107

3.9.5 Multivariate analysis of the association between short-term bowel function, maternal, intrapartum, OASIS and neonatal characteristics and long-term bowel function 113

3.9.6 Bowel function and Endoanal Ultrasound Scan findings 117

3.9.7 Quality of Life scores 123

3.9.8 Multivariate analysis of the association between short-term bowel function following OASIS, maternal, intrapartum, OASIS and neonatal characteristics and long-term QoL 127

3.9.9 Multivariate analysis of the association between long-term bowel function, maternal, intrapartum, OASIS and neonatal characteristics and long-term QoL 134

3.9.10 Analysis of data for women sustaining OASIS following introduction of RCOG Green-top Guideline 143

3.10 Discussion 144

3.10.1 Strengths and limitations 153

3.10.2 Summary 155

4 COHORT STUDY OF THE EFFECT OF BIRTH AND ITS MODE AFTER ANAL SPHINCTER INJURY ON BOWEL FUNCTION AND QUALITY OF LIFE (THE BASIQ STUDY) 157

4.1 Introduction 157

4.2 Aim and Objectives 158

4.2.1 Aim 158

4.2.2 Objectives 158

4.3 Study Design 159

4.4 Population 160

4.4.1 Exclusion criteria: 160

4.5 Outcome measures 160

4.6 Sample Size 161

4.7 Recruitment to the study 162

4.8 Data Collection 163

4.8.1 Antenatal study participant baseline characteristics 164

4.8.2 Bowel function and QoL – at 34 gestational weeks and 6 months postnatal 164

4.8.3 Subsequent birth information 165

4.8.4 Endoanal Ultrasound scan findings – ante- and post- subsequent birth 165

4.9 Data Analysis..... 165

4.9.1 Definition of characteristics..... 165

4.9.2 Statistical methods 170

4.10 Ethical approval 170

4.11 Results.....171

4.11.1 Cohort sample - recruitment and follow-up rates..... 171

4.11.2 Baseline characteristics of women recruited to the study..... 173

4.11.3 Baseline characteristics of women who completed postnatal MHQ 183

4.11.4 Mode of study birth: choice and actual 190

4.11.5 Bowel function following study birth..... 198

4.11.6 QoL scores following subsequent birth..... 210

4.11.7 Mode of study birth on bowel function and QoL 223

4.11.8 Endoanal scan findings following subsequent birth 235

4.11.9 Subsequent vaginal birth – repeat OASIS and perineal trauma 248

4.11.10 Multivariate analysis of antenatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on bowel function post study birth..... 249

4.11.11 Multivariate analysis of antenatal bowel function and QoL scores, maternal, intrapartum, OASIS and neonatal characteristics on QoL scores post study birth 254

4.11.12 Multivariate analysis of postnatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on QoL scores post study birth 263

4.11.13 Analysis of data for women sustaining OASIS following introduction of RCOG Green-top Guidelines 271

4.12 Discussion 272

4.12.1 Strengths and limitations 278

4.12.2 Summary 284

5 THESIS DISCUSSION AND CONCLUSION 286

5.1 Discussion of overall thesis findings 286

5.1.1 Strengths and limitations 292

5.2 Overall thesis conclusion 296

Appendix 1.1 RCOG Green-top Guidelines standardised evidence levels and grades of recommendations 298

Appendix 1.2 Manchester Health Questionnaire (MHQ) – Scoring calculation 299

Appendix 2.1 PRISMA 2009 Checklist 300

Appendix 2.2 Medline search strategies 303

Appendix 2.3 Characteristics of all studies included in the systematic review……. 305

Appendix 2.4 Characteristics of the studies included in the systematic review meta analyses 315

Appendix 2.5 Excluded full-text articles from the systematic review with reason for exclusion 324

Appendix 3.1 Postal Questionnaire 329

Appendix 3.2 Multivariate analysis of short-term bowel function, maternal intrapartum, OASIS and neonatal characteristics on long-term bowel function – respondents post 2002 342

Appendix 3.3 Multivariate analysis of short-term bowel function, maternal, intrapartum, OASIS and neonatal characteristics on long-term QoL – respondents post 2002 344

Appendix 3.4 Multivariate analysis of long-term bowel function, maternal intrapartum, OASIS and neonatal characteristics on long-term QoL – respondents post 2002 349

Appendix 4.1 STROBE Statement—Checklist of items that should be included in reports of cohort studies 355

Appendix 4.2 BASIQ Study antenatal information data capture form 357

Appendix 4.3 BASIQ study MHQ 360

Appendix 4.4 BASIQ study postnatal information data capture form 366

Appendix 4.5 Endoanal scan results data form 369

Appendix 4.6 BASIQ Study consent form 370

Appendix 4.7 Multivariate analysis of antenatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on bowel function post the study birth for women who sustained OASIS after January 2002 371

Table 4.8 Multivariate analysis of antenatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on QoL post the study birth for women who sustained OASIS after January 2002 373

Table 4.9 Multivariate analysis of postnatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on QoL post the study birth for women who sustained OASIS after January 2002 379

References..... 385

List of figures

Figure 1.1 Illustration of second degree childbirth related perineal trauma..... 31

Figure 1.2 Illustration of a fourth degree OASIS 31

Figure 1.4 Ultrasound image showing the normal anatomy of the anal canal..... 37

Figure 1.5 Normal ultrasound image of the deep level of the anal canal. 39

Figure 1.6 Normal ultrasound image of the mid level of the anal canal 40

Figure 1.7 Normal ultrasound image of the superficial level of the anal canal 41

Figure 2.1 PRISMA 2009 Flow chart 61

Figure 2.2 Quality assessment criteria for 25 included cohort NRSs using Joanna Briggs Institute Prevalence Critical Appraisal Tool 63

Table 2.3 Quality assessment criteria for two included case control NRSs using Newcastle-Ottawa Quality Assessment Scale..... 65

Figure 2.3 Reported incidence of AI in women with previous OASIS: no subsequent birth versus subsequent birth 68

Figure 2.4 Incidence of AI in women with previous OASIS: ≥ 2 subsequent births versus 1 subsequent birth. 71

Figure 2.5 Incidence of AI in women with previous 4th degree OASIS: ≥ 2 subsequent births versus 1 subsequent birth. 71

Figure 2.6 Reported incidence of AI in women with previous OASIS: Pre- versus post-subsequent birth..... 73

Figure 2.7 Incidence of worsening or de novo symptoms of AI in women with previous OASIS: subsequent vaginal birth versus subsequent caesarean section . 75

Figure 2.8 Reported incidence of AI in women with previous OASIS sustained 2003 onwards: no subsequent birth versus subsequent birth 78

Figure 2.9. Reported incidence of AI in women with previous OASIS sustained 2003 onwards: pre- versus post-subsequent birth 80

Figure 2.10. Incidence of worsening of or de novo symptoms of AI in women with previous OASIS sustained 2003 onwards: subsequent vaginal birth versus subsequent caesarean section..... 82

Figure 3.1 Flow chart to show postal questionnaire responses 97

Figure 4.1 Recruitment and follow-up rates..... 172

Figure 5.1 Incidence of worsening or de novo symptoms of AI in women with previous OASIS: pre- versus post-subsequent vaginal birth 289

Figure 5.2 Incidence of worsening or de novo symptoms of AI in women with previous OASIS: subsequent vaginal birth versus subsequent caesarean section 291

List of tables

Table 1.1 Classification of OASIS and other childbirth related perineal trauma ... 30

Table 1.2 Normal anal resting and squeeze pressures 46

Table 1.3 Recommended questionnaires for AI symptoms and impact on QoL ... 48

Table 2.1 Quality assessment criteria for cohort NRSs using Joanna Briggs Institute Prevalence Critical Appraisal Tool 58

Table 2.2 Quality assessment criteria for case control NRSs using Newcastle-Ottawa Quality Assessment Scale 59

Table 3.1 Baseline characteristics of postal questionnaire responders and non-responders…….. 100

Table 3.2 Birth mode history for questionnaire responders 103

Table 3.3 Baseline characteristics of questionnaire responders in relation to recollection of sustaining OASIS 105

Table 3.4 Bowel symptoms at questionnaire completion..... 108

Table 3.5 Relationship between bowel symptoms of poor control of flatus and faecal urgency at postnatal questionnaire completion and post OASIS births 110

Table 3.6 Relationship between bowel symptoms of faecal leakage at postnatal questionnaire completion and post OASIS births 110

Table 3.7 Comparison of bowel symptoms of flatus control and faecal urgency at initial hospital clinic review and at postal questionnaire completion 112

Table 3.8 Comparison of bowel symptoms of faecal leakage at initial hospital clinic review and at postal questionnaire completion..... 112

Table 3.9 Multivariate analysis of the association between short-term bowel function, maternal intrapartum, OASIS and neonatal characteristics and long-term bowel function 115

Table 3.10 Baseline characteristics of women having EAUS and no EAUS. 118

Table 3.11 Bowel function at questionnaire completion for respondents who had EAUS…… 121

Table 3.12 Bowel function at questionnaire completion for women with extensive scarring or sphincter defect on EAUS 122

Table 3.13 MHQ QoL domain scores for questionnaire respondents..... 124

Table 3.14 The relationship between the total number bowel symptoms and the QoL domains scores 126

Table 3.15 Multivariate analysis of the association between short-term bowel function at initial hospital clinic review following OASIS, maternal, intrapartum, OASIS and neonatal characteristics and long-term QoL. 129

Table 3.15 Multivariate analysis of the association between long-term bowel function following OASIS, maternal, intrapartum, OASIS and neonatal characteristics and long-term QoL. 137

Table 4.1 Characteristic definition of bowel symptoms for data analysis 167

Table 4.2 Characteristic classification of QoL scoring for data analysis..... 168

Table 4.3 Definitions of birth characteristics for data analysis..... 169

Table 4.4 Baseline characteristics of all participants with comparison between women who completed the postnatal MHQ and those who did not..... 175

Table 4.5 Baseline characteristics of all participants bowel function with comparison between women who completed postnatal MHQ those who did not... 178

Table 4.6 Baseline characteristics of all participants antenatal QoL with comparison of women who completed the postnatal MHQ and those who did not 181

Table 4.7 Baseline characteristics of participants –postnatal clinic follow-up and postnatal postal follow-up 184

Table 4.8 Baseline characteristics of participants bowel function –postnatal clinic follow-up and postnatal postal follow-up 186

Table 4.9 Baseline characteristics of participants QoL –postnatal clinic follow-up and postnatal postal follow-up 188

Table 4.10 A comparison of chosen mode of study birth and anal sphincter integrity 192

Table 4.11 Reasons women gave for pursuing planned mode of study birth 193

Table 4.12 Women who did/ did not get planned mode of study birth 195

Table 4.13 Actual mode of study birth in relation to the initial OASIS classification 197

Table 4.14 Bowel symptoms at postnatal MHQ completion 199

Table 4.15 Comparison of bowel urgency at antenatal MHQ completion and at postnatal MHQ completion 201

Table 4.16 Comparison of poor control of flatus at antenatal MHQ completion and at postnatal MHQ completion 202

Table 4.17 Comparison of difficulty wiping clean at antenatal MHQ completion and at postnatal MHQ completion 203

Table 4.18 Comparison of faecal leakage – passive only at antenatal MHQ completion and at postnatal MHQ completion 204

Table 4.19 Comparison of faecal leakage when coughing/sneezing at antenatal MHQ completion and at postnatal MHQ completion 205

Table 4.20 Comparison of faecal leakage with walking at antenatal MHQ completion and at postnatal MHQ completion 206

Table 4.21 Comparison of faecal leakage during SI at antenatal MHQ completion and at postnatal MHQ completion 207

Table 4.22 Comparison of faecal leakage - loose at antenatal MHQ completion and at postnatal MHQ completion 208

Table 4.23 Comparison of bowel symptoms at postnatal MHQ completion and at antenatal MHQ completion 209

Table 4.24 Postnatal MHQ QoL domain scores 211

Table 4.25 Comparison of MHQ General Health Perception (GHP) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion……..... 213

Table 4.26 Comparison of MHQ Incontinence Impact (II) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion..... 214

Table 4.27 Comparison of MHQ Role Limitations (RL) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion..... 215

Table 4.28 Comparison of MHQ Physical Limitations (PL) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion..... 216

Table 4.29 Comparison of MHQ Social Limitations (SL) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion..... 217

Table 4.30 Comparison of MHQ Personal Relationships (PR) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion. 218

Table 4.31 Comparison of MHQ Emotions (E) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion 219

Table 4.32 Comparison of MHQ Sleep/Energy (SE) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion..... 220

Table 4.33 Comparison of MHQ Severity Measure (SM) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion..... 221

Table 4.34 Comparison of QoL domain scores at postnatal MHQ completion and at antenatal MHQ completion..... 222

Table 4.35 Baseline maternal characteristics – study birth mode vaginal birth or caesarean section..... 225

Table 4.36 Baseline bowel function at antenatal MHQ completion – study birth mode vaginal birth or caesarean section..... 227

Table 4.37 Baseline QoL score at antenatal MHQ completion – study birth mode vaginal birth or caesarean section..... 229

Table 4.38 Comparison of changes in bowel symptom frequency prior to and following study birth by mode of birth..... 232

Table 4.39 Comparison of changes in MHQ QoL scores prior to and following study birth by mode of birth..... 234

Table 4.40 EAUS findings for women prior to and following the study birth 237

Table 4.41 Bowel function for women who had EAUS following subsequent birth – all modes of birth..... 239

Table 4.42 Comparison of a negative impact on QoL following study birth by presence/absence of extensive scarring or defect – all modes of birth..... 241

Table 4.43 Comparison of worsening, no change or improvement in bowel symptoms by the presence/absence of extensive scarring or defect following study birth – all modes of birth..... 243

Table 4.44 Comparison of worsening or no worsening in bowel symptoms by the presence/absence of extensive scarring or defect following study birth – all modes of birth..... 245

Table 4.45 Comparison of changes in MHQ QoL scores prior to and following study birth for women with no sphincter abnormality or extensive scarring or defect by mode of study birth 247

Table 4.46 Multivariate analysis of antenatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on bowel function post study birth 252

Table 4.47 Multivariate analysis of antenatal bowel function and QoL scores, maternal, intrapartum, OASIS and neonatal characteristics on QoL scores post study birth 257

Table 4.48 Multivariate analysis of postnatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on QoL scores post study birth . 266

List of abbreviations

Abbreviation	
AI	Anal Incontinence
BMI	Body Mass Index
CI	Confidence Interval
EAS	External Anal Sphincter
EAUS	Endoanal Ultrasound
IAS	Internal Anal Sphincter
ICS	International Continence Society
IQR	Inter Quartile Range
LREC	Local Research Ethics Committee
MHQ	Manchester Health Questionnaire
NHS	National Health Service
NRES	National Research Ethics Service
NRSs	Non-Randomised Study(s)
OASIS	Obstetric Anal Sphincter Injury(s)
OR	Odds Ratio
aOR	Adjusted Odds Ratio
QoL	Quality of Life
RCM	Royal College of Midwives
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised Controlled Trial
RR	Relative Risk
SAE	Stamped Addressed Envelope
SD	Standard Deviation

1 LITERATURE AND CLINICAL PRACTICE REVIEW

1.1 Introduction

Approximately 70-80% of women who give birth vaginally will sustain childbirth related perineal trauma, either through a spontaneous tear or surgical cut (episiotomy) (1). This perineal trauma can sometimes extend into the anal sphincter muscles and is known as Obstetric Anal Sphincter Injuries (OASIS). OASIS are further classified as third or fourth degree tears whereby a third degree tear involves a partial or complete disruption of the anal sphincter complex (external and internal anal sphincters), and a fourth degree tear which involves complete disruption of the anal sphincter complex and the anal epithelium (see section 1.1.4).

OASIS is recognised as the most common cause of anal incontinence (AI) in childbearing age women (2), encompassing symptoms of flatus incontinence, passive soiling, incontinence of liquid or solid stool and faecal urgency. These symptoms can have severe social and psychological implications for the women and their families. AI is a distressing and disabling condition and the symptoms can cause social and hygienic problems that lead to isolation, limiting occupational and social activity, negative effect on sexual function and consequent impact on relationships, reduced self-esteem and reduced quality of life (QoL) (3-6). Incidence of AI is often under reported by women due to feelings of embarrassment or regarded as an expected consequence of a vaginal birth (3, 5, 6). In fact AI has been called the ‘unvoiced symptom’ due to the embarrassment experienced by women who suffer from it (5). The reported incidence of AI in women with OASIS ranges

from 41% to 61% and is two to three times higher than for women who do not sustain an OASIS during childbirth (7-9).

1.1.1 OASIS incidence

The reported worldwide incidence of OASIS varies due to the many variables that contribute to its cause, however, published studies report an incidence of between 4% and 6.6% of vaginal births (10-13). In the UK, for women undergoing their first vaginal birth of a singleton, cephalic baby, the incidence of OASIS has tripled over the ten year period from 1.8% in 2002 to 5.9% in 2012 (14). The authors of this paper concluded that the most likely explanation for the threefold increase in reported OASIS was due to improved detection of OASIS following the introduction of RCOG evidence based Green-top guidelines in 2001 (revised in 2007 and 2015) (15), improved clinician training and improvements in the UK HES data capture system, rather than changes in maternal and intrapartum risk factors. A national survey indicated that the overall incidence in the UK is 2.9% for all vaginal births, with incidences of 6.1% and 1.7% for nulliparous and multiparous women respectively (16).

1.1.2 OASIS risk factors

Since the year 2000, a large number of studies using data from national birth registers have been published from countries including Eire, Israel, Netherlands, Norway, the UK and the USA. The benefit of such studies over smaller retrospective studies is that the data from the registry studies are more robust and reliable and with less risk of bias due to the large data sets involved. Risk factors for OASIS can be grouped into maternal, intrapartum and neonatal characteristics. However, due to

the multifactorial nature of childbirth it is difficult to identify the causality between some of the individual risk factor characteristics as some are associated interactions.

Maternal risk factors for OASIS.

Nulliparous women have a higher risk of OASIS than parous women who have had a previous vaginal birth with several registry studies showing a two to seven fold increase in risk (10, 17-19) and the risk increment of nulliparity is markedly higher than that of any other maternal risk factor. However, for parous women whose previous births were by caesarean section only, they have a higher risk of OASIS than nulliparous women undergoing their first vaginal birth with a range of adjusted odds ratios (aOR) of 1.2-1.42 (10, 17, 18, 20). Women with a higher maternal age have an increased risk of OASIS with studies showing that a maternal age of over 30 years being a risk factor (aOR 1.07) (21), or women with a maternal age of over 35 years (aOR 1.09-1.6) (17). Interestingly, Gerdin et al (2007) found that maternal age of over 35 years was only a significant risk factor when the neonatal birthweight was less than 4000 gms (OR 1.1) (22). Ampt et al (2012) (20) found an association between OASIS and older maternal age regardless of parity whereas Landy et al (2011) found that older maternal age was only significant for women who were nulliparous (23). The risk of a younger maternal age differed across studies, however, an age less than 20 years was found to have a reduced risk in some studies (10, 17, 20, 24) but an increased risk in two others (25, 26). In comparison to white Caucasian women, Asian ethnicity has been found to be a significant risk factor for OASIS with a range of aORs of 1.37-2.5 (10, 17, 20, 23), whereas Black and Hispanic ethnicity has been shown to have a protective effect (aOR 0.69) (17). However, Baghestan et al (2012) showed an increased risk for women of Black

ethnicity (10) and the conflicting study findings may be due to definitions used within the studies for the terms of ethnicity.

Intrapartum risk factors for OASIS

Operative vaginal births are associated with an increased risk of OASIS compared to spontaneous vaginal birth and the type of instrument used is important. A Cochrane systematic review involving 10 RCTs found that birth using forceps had a significantly higher risk for sustaining an OASIS (OR 1.89) when compared to operative birth using vacuum extraction (ventouse or kiwi) (27). Likewise, large registry studies have shown that when adjusting for other variables forceps birth is a higher risk for OASIS compared to vacuum extraction (with a range of aORs of 1.45-8.2) (10, 17, 20, 23, 24, 28). A prolonged second stage of birth of greater than 60 minutes has been shown to be an independent risk factor for OASIS from several large registry studies (with a range of aORs of 1.49-5.4) (17, 23, 24). Landy et al (2011) also demonstrated that the risk of OASIS increased with each 60 minute lengthening in second stage (23). There is discrepancy in the reported literature with regards to the association between episiotomy and OASIS and this is probably a reflection of the difference in types of episiotomies assessed and the variation in the cutting angle of episiotomies (29, 30). In a large registry study De Leeuw et al (2008) found that a mediolateral or lateral episiotomy reduced the risk of OASIS when performed during a forceps birth (OR 0.08) or a vacuum assisted birth (OR 0.11) (31), a finding that has been supported by other large registry studies (24, 32, 33). However, a smaller study found mediolateral episiotomy to be associated with a higher risk of OASIS (OR 4.04) but following adjustment for other risk factors the type of episiotomy no longer remained a risk factor (34). Consequently, the

evidence suggests mediolateral episiotomy does not increase the risk of OASIS for nulliparous women undergoing an operative birth.

Neonatal risk factors for OASIS

A birthweight greater than 4000 gms is one of the largest risk factors for OASIS (with a range of aORs of 2.17-9.2) that has been confirmed by many large registry studies (10, 17, 23, 24) and with a birthweight greater than 4500 gms the risk of sustaining an OASIS is even greater (aOR 10.5-13.6) (24). Even though the risk of OASIS is increased with a greater birthweight the majority of OASIS occur with babies of a birthweight less than 4000 gms since a very high birthweight is not common (17, 20, 23, 32, 35). An occipito-posterior presentation of the baby during the birth has been shown to be an increased risk factor for OASIS (with a range of aORs of 1.73-3.2) (28, 33). However, the incidence of this fetal position is very low and is often assisted with either forceps or vacuum extraction that consequently increases the OASIS risk due to the previously discussed known associations of these operative birth modes.

In view of the risk factors for OASIS being known studies have attempted to investigate the possibility of developing a prognostic model to identify women at risk. (36, 37). However the clinical utility of such prognostic models has yet to be proven. A previous study by the author of this thesis, (Webb et al (2016)), showed that despite being able to prove the feasibility of developing a statistically robust prognostic model to identify individualised risk for OASIS using demographic and obstetrics factors known prior to the birth, this could not demonstrate its projected usefulness in a clinical setting to ‘rule in’ an OASIS and the high false positive rate

would only lead to undue anxiety and, potentially, higher risk of intervention. Also, although recent studies have shown the intrapartum intervention of manual perineal protection has been shown to reduce the incidence of OASIS (11, 38, 39), many women will still sustain an OASIS during vaginal childbirth. It is therefore vital that the long-term impact of having a subsequent birth is investigated in order to assist women who sustain an OASIS and their clinicians when considering and deciding on the mode of this subsequent birth. In an age where all practice and recommendations should be evidence based it is important that the association between previous OASIS, further birth and its mode be established.

This thesis aims to add to the research evidence available by using a combination of studies to provide a better understanding both of the longer-term impact on bowel function and Quality of Life (QoL) for women who sustain an OASIS and the impact of a subsequent birth and its mode on changes in bowel function and Quality of Life (QoL) for women with a previous OASIS.

1.1.3 Royal College of Obstetricians and Gynaecologists (RCOG) recommendations for the management of OASIS

The RCOG Green-top Guidelines are systematically developed recommendations created to assist clinicians and patients in making decisions about the most appropriate treatment and condition management. They are concise documents providing specific practice recommendations based on published evidence on areas of obstetric and gynaecological clinical practice and are produced under the direction of the RCOG Guidelines Committee. Recommendations provided within the Green-top Guidelines are not intended to be used to command a specific course of

management by clinicians but as a guide to best practice as treatment must be evaluated with reference to the individual patient needs and local resources. The Green-top guidelines are produced with the intent that the clinical recommendations will be incorporated into local NHS Trust guidelines and protocols.

The RCOG Green-top guideline 'The Management of Third- and Fourth-Degree Perineal Tears; Green-top Guideline No. 29' concerning the diagnosis, management and treatment of OASIS, was first published in July 2001 (15). It has since been revised twice, once in March 2007 and most recently in July 2015 which was the guideline currently in use at the time this thesis was written (40). All clinical recommendations from the RCOG Green-top Guideline No.29 have been incorporated into the NHS Trust guidelines for the management of OASIS at Birmingham Women's and Children's NHS Foundation Trust since their first publication in 2001 and updated accordingly in line with Green-top Guideline revisions. Therefore, throughout this thesis, definitions for OASIS classification, OASIS repair and the management of a subsequent birth for women with a previous OASIS are as per the RCOG Green-top Guideline No.29 and described in the sections 1.1.4, 1.1.5 and 1.1.6, respectively.

1.1.4 OASIS classification

Table 1.1 is a summary of the classification of childbirth related perineal trauma which includes OASIS that was first described by Sultan et al (1999) and has since been adopted by both the International Consultation on Incontinence (41) and the RCOG. These classifications of childbirth related perineal trauma are illustrated in figures 1.1 and 1.2.

Table 1.1 Classification of OASIS and other childbirth related perineal trauma

	Childbirth Related Perineal Trauma Classification	
	First degree tear	Injury to perineal skin and/or vaginal epithelium
	Second degree tear	Injury to perineum involving perineal muscles but not involving the anal sphincter complex
OASIS encompass both third and fourth degree tears	Third degree tears:	
	3A tear	Less than 50% of the external anal sphincter (EAS) torn
	3B tear	More than 50% of the EAS torn
	3C tear	Both EAS and internal anal sphincter (IAS) torn
	Fourth degree tear	Injury to the perineum involving the anal sphincter complex (EAS & IAS) and anal epithelium

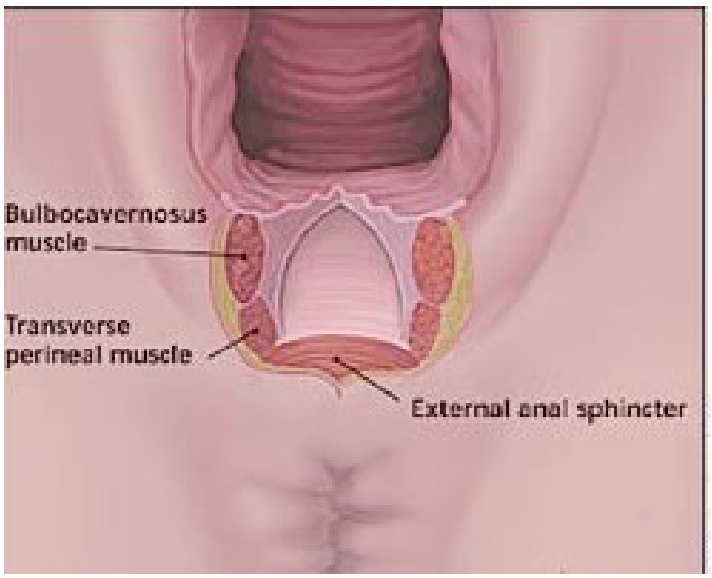


Figure 1.1 Illustration of second degree childbirth related perineal trauma

Copyright © Ciné-Med, Inc. Permission for reproduction requested.

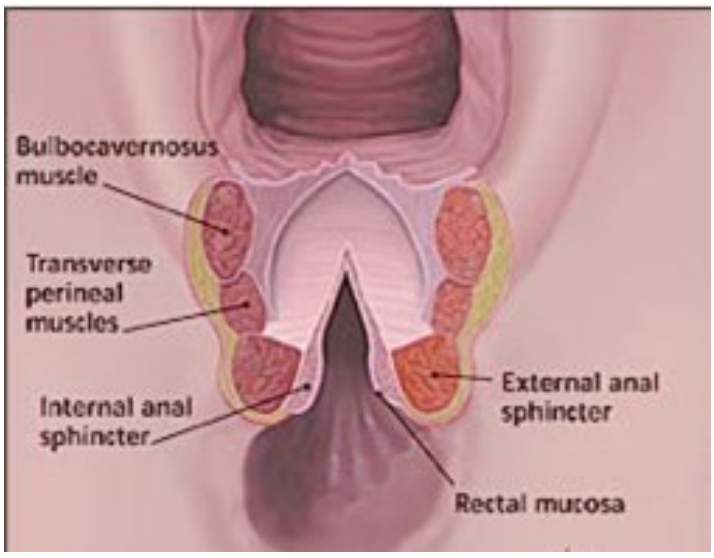


Figure 1.2 Illustration of a fourth degree OASIS

Copyright © Ciné-Med, Inc. Permission for reproduction requested.

1.1.5 Method of OASIS repair

To optimize the outcome from OASIS repair it is important that the most appropriate repair technique is used. There are two techniques for repair of the external anal sphincter (EAS), either an ‘end-to-end’ technique by which the damaged ends are sutured by approximation, or an ‘overlap’ technique whereby the damaged ends are placed one on top of the other and sutured to create an overlapping of the muscle. For a full thickness EAS tear either an ‘end-to-end’ or ‘overlap’ technique can be used as a Cochrane review of six randomized controlled trials involving 588 women showed no difference in outcomes between these two repair methods (42). However, for a partial thickness EAS tear, such as 3A OASIS or a 3B that does not extend through 100% of the EAS, an ‘end-to-end’ repair technique should be used as, in a small study of 32 women, Sultan et al (1999) demonstrated that overlap technique when used to repair a partial EAS tear exerted undue tension on the repair (43).

The internal anal sphincter (IAS) is smooth muscle which has less fibrous tissue than striated muscle and it is more likely to tear when placed under tension. Consequently, to minimize this potential risk tears to the IAS should be repaired separately by using an ‘end-to-end’ technique (43).

A torn anorectal mucosa should be repaired by approximation using either a continuous or interrupted technique (43).

1.1.6 Recommendations for mode of subsequent birth for women with previous OASIS

For women who have previously sustained an OASIS the recommendation in the RCOG Green-top guideline is that they should be counselled about the mode of a subsequent birth. It states that any woman with a previous OASIS who has bowel symptoms, abnormal endoanal ultrasonography and/or manometry should be counselled regarding the option of an elective caesarean section. An abnormal endoanal ultrasonography can be one of two things: firstly, it can be the presence of a 'defect' which is a clear break to the circular structure of the EAS and/or IAS muscles, secondly it can be an area of scarring that is greater than 30 degrees in width and is classified as 'excessive scarring' (44).

The evidence used within RCOG Green-top guidelines is classified into standardisd evidence levels and grades of recommendations. These are provided in Appendix 1.1. The RCOG Green-top current recommendations regarding subsequent birth mode for women with a previous OASIS are graded as 'recommended best practice based on the clinical experience of the Green-top guideline development group'. This is the lowest classification of evidence level as the only available evidence underpinning these recommendations at the time of guideline publication was expert opinion that is graded as evidence level four. More robust evidence is therefore needed.

1.2 Endoanal ultrasound, manometry and image interpretation

1.2.1 Anatomy of the anal canal

It is vital that clinicians caring for women undergoing pregnancy and birth have an understanding of the anatomy of the anal canal and its complexity. The anal canal is the most terminal part of the lower gastrointestinal tract or large intestine and is between two and four centimetres in length. The internal anal sphincter (IAS) is a continuation of the circular smooth rectal wall muscle. The longitudinal layer of the anal canal is an extension of the outer longitudinal layers of the muscularis propria. The external anal sphincter (EAS) is longitudinal muscle that arises from the levator ani and puborectalis muscles that extend around and enclose the IAS. The levator ani is a thin muscle arising from the sidewall of the pelvic bone that supports the contents of the pelvis and separates the ischio-rectal fossa from the overhead supra levator space. The puborectalis muscle stems from the pubis and forms a sling of muscle around the anorectal junction.

The EAS is further divided into three distinct levels which are shown on the coronal view of the anal canal in figure 1.3:

Deep (proximal) level – where the EAS joins with the fibres from the puborectalis muscle

Superficial (middle) level – where the EAS is anteriorly attached to the superficial transverse perineii and posteriorly inserted into the coccyx via the anococcygeal ligament

Subcutaneous (distal) level – where the EAS extends below the terminus of the IAS

The anterior of the anal canal differs between males and females. In men the anal sphincter is symmetrical at all of the three levels whereas in women the muscle fibres unite anteriorly in the inferior portion. Consequently, endoanal imaging above this level may give a false impression of a deficiency in the muscle. The anal canal can also be significantly shorter in women compared to men.

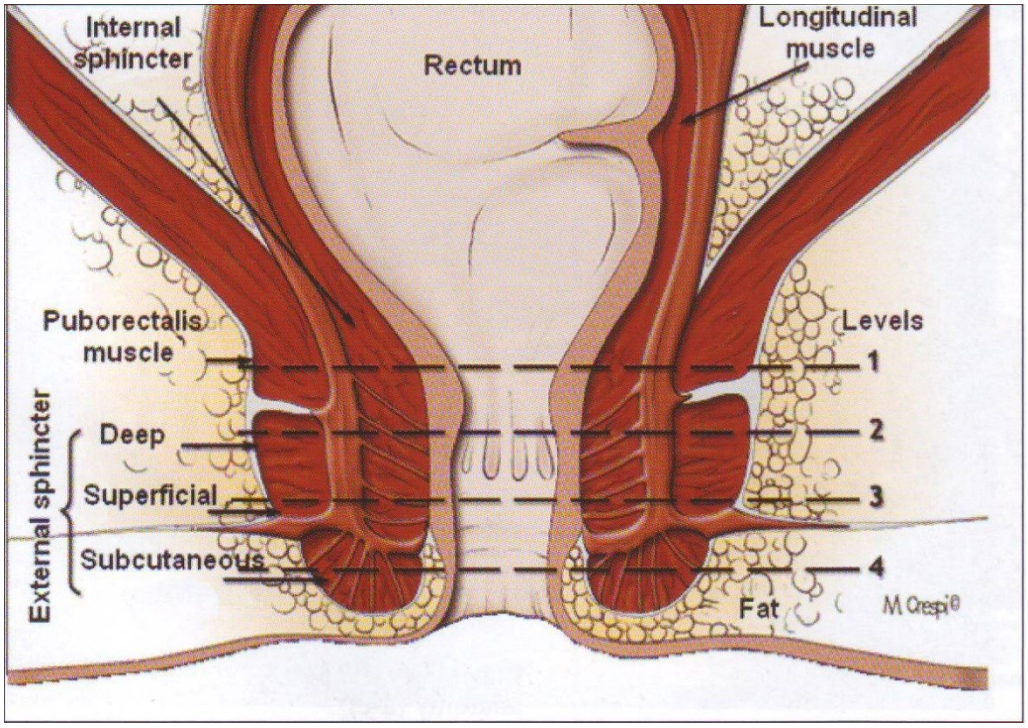


Figure 1.3 Coronal view of the anal canal

Reproduced from Atlas of Endoanal and Endorectal Ultrasonography (45). Permission for reproduction requested.

1.2.2 Endoanal Ultrasound

Endoanal ultrasound (EAUS) is regarded as the gold standard for evaluating anal sphincter pathology for investigations of anal incontinence and anal sphincter integrity (46). Ultrasonography uses the method of visualisation of structures by reflection whereby the energy of the ultrasonic wave is reflected back by the tissues. The echogenicity of any structure is characterised by the level of echoes within (its reflectivity) and can be hyper- (highest reflectivity, appears white) or hypoechoic (lowest reflectivity, appears black). EAUS has facilitated the definition of the anal canal anatomy into the following six distinct structural layers (inner to outer) (Figure 1.4):

1. Hyperechoic: interface with the hard cone.
2. Hypoechoic: anal mucosa.
3. Hyperechoic: sub-epithelial tissues.
4. Hypoechoic: internal anal sphincter (IAS).
5. Hyperechoic: longitudinal muscle.
6. Mixed echogenicity: external anal sphincter (EAS).

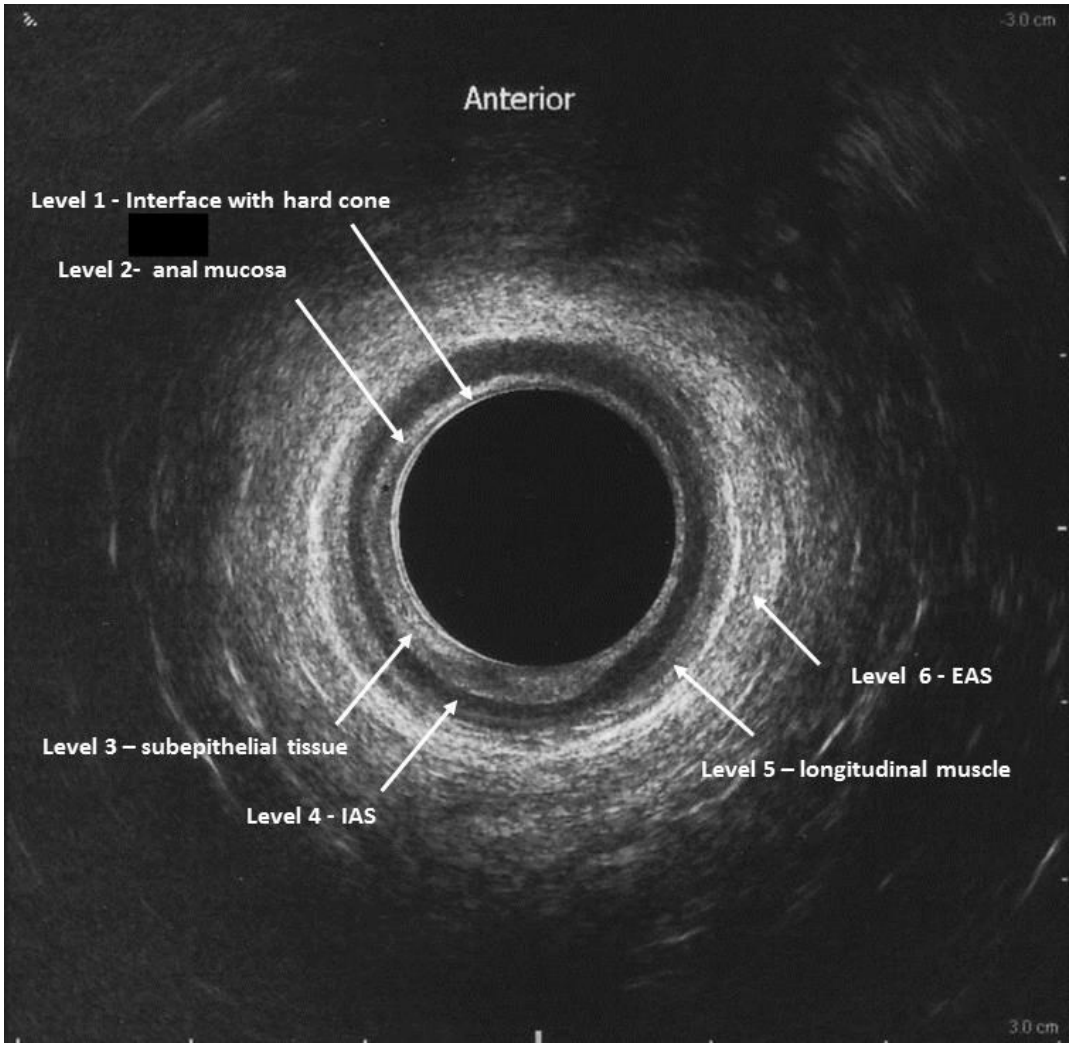


Figure 1.4 Ultrasound image showing the normal anatomy of the anal canal.

Endoanal images are reviewed by dividing them into three layers (47), as follows:

1. Deep: this shows the sling of the puborectalis and the deep part of the external anal sphincter (Figure 1.5).
2. Mid: this layer visualises the anococcygeal ligament, superficial part of the external anal sphincter, internal anal sphincter, perineal body and the vagina (Figure 1.6).
3. Superficial: this layer shows only the subcutaneous part of the external anal sphincter (Figure 1.7).

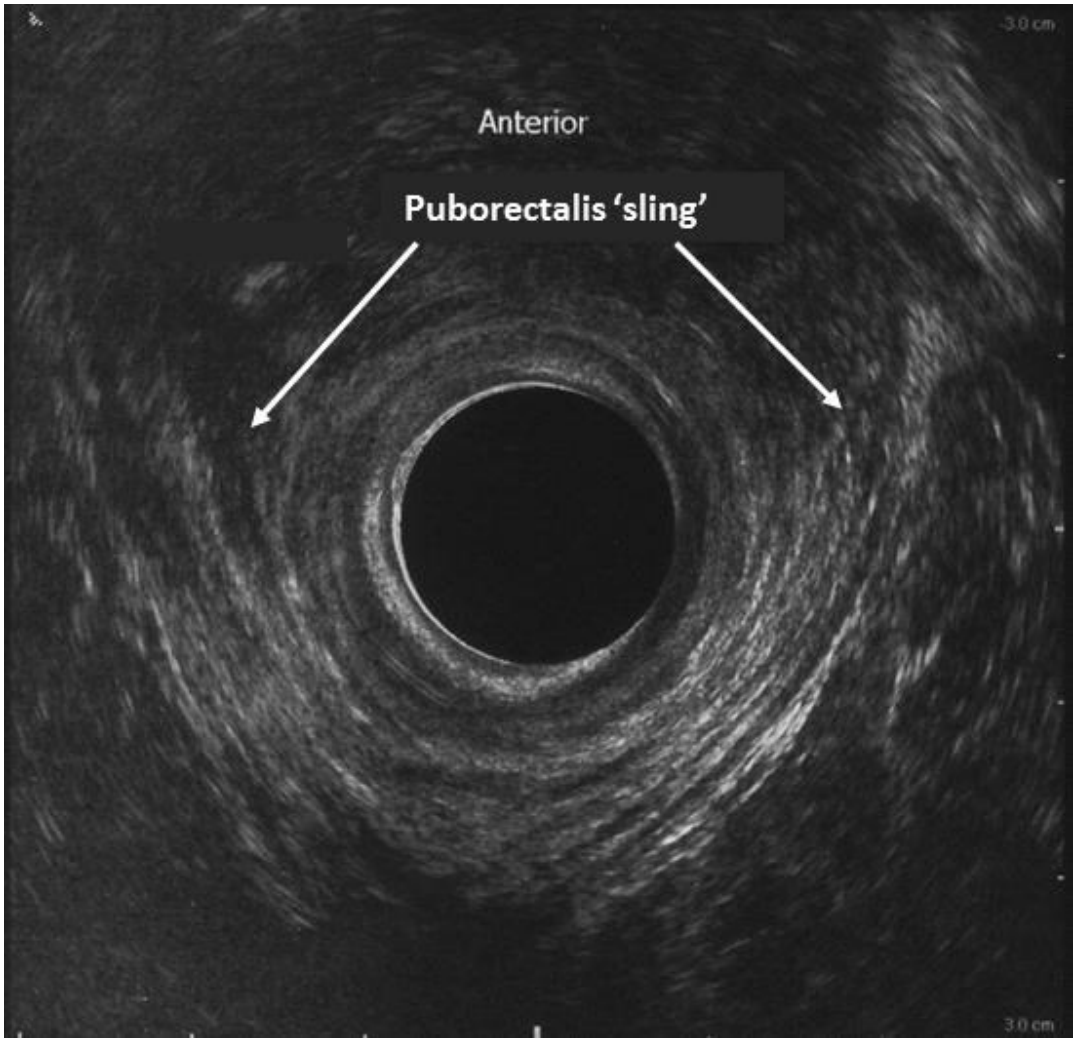


Figure 1.5 Normal ultrasound image of the deep level of the anal canal.

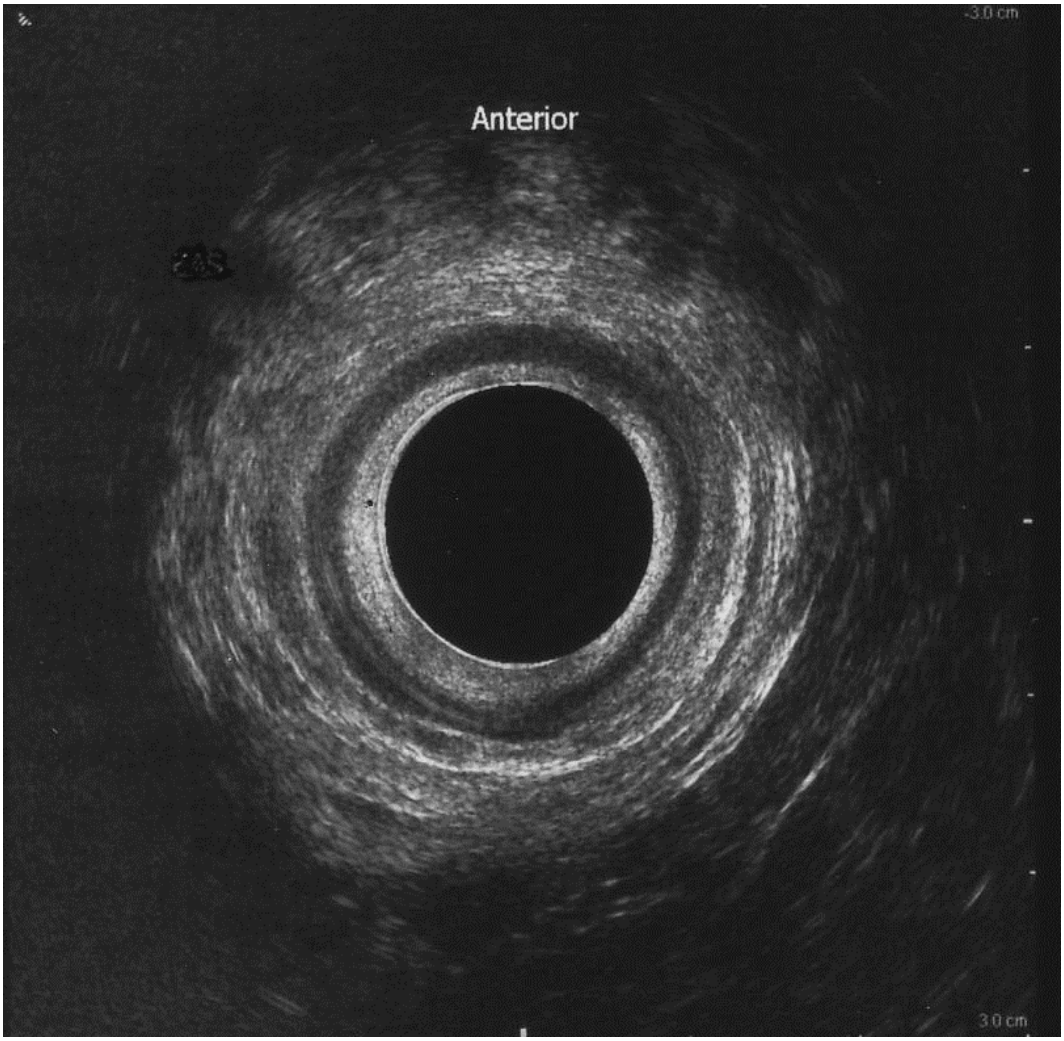


Figure 1.6 Normal ultrasound image of the mid level of the anal canal

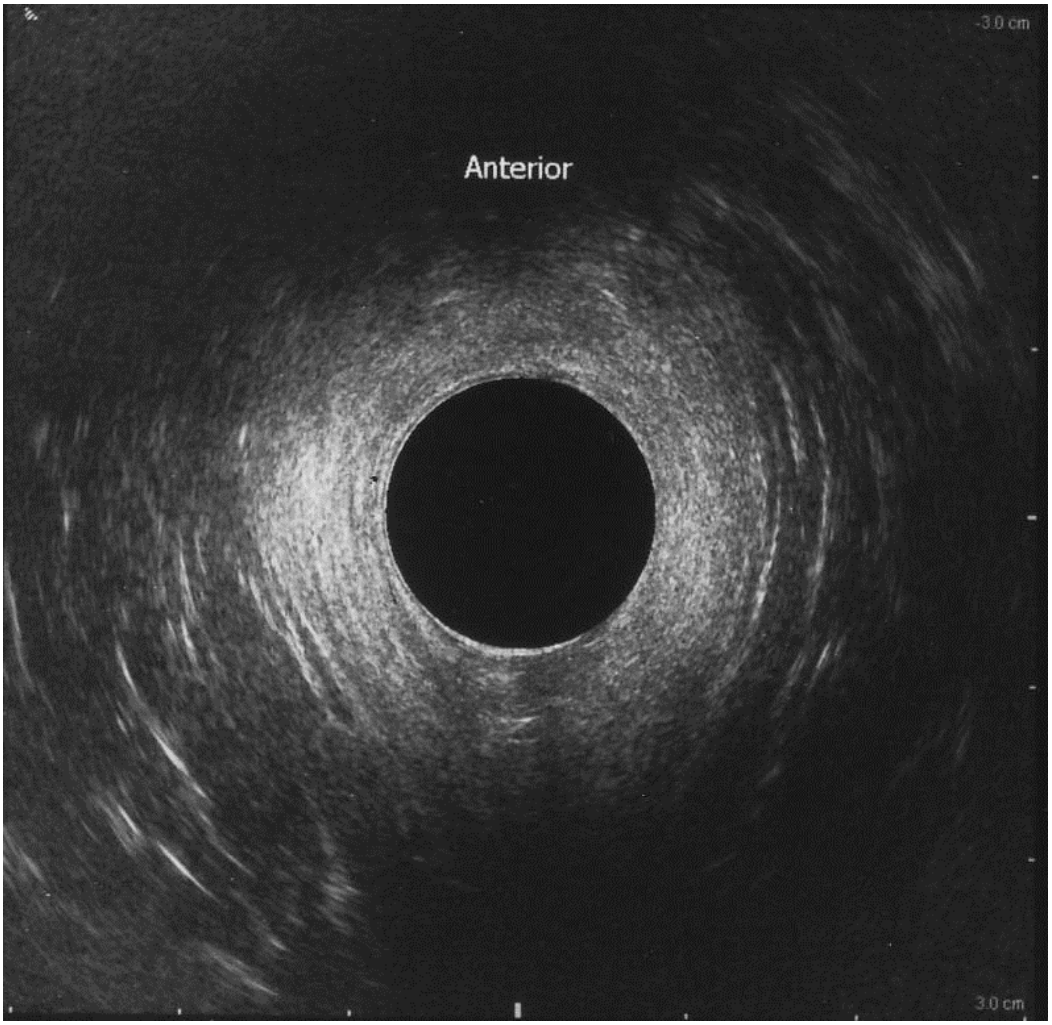


Figure 1.7 Normal ultrasound image of the superficial level of the anal canal

A defect or excessive scarring in the external anal sphincter is demonstrated by a hypoechoic area that is present in the area where the muscle is disrupted and can be partial or full thickness (Figure 1.8). A defect in the internal anal sphincter is demonstrated by a hyperechoic area that is present in the area where the muscle is disrupted and is sometimes accompanied by thickening of the damaged ends of the muscle resulting from retraction (Figure 1.9).

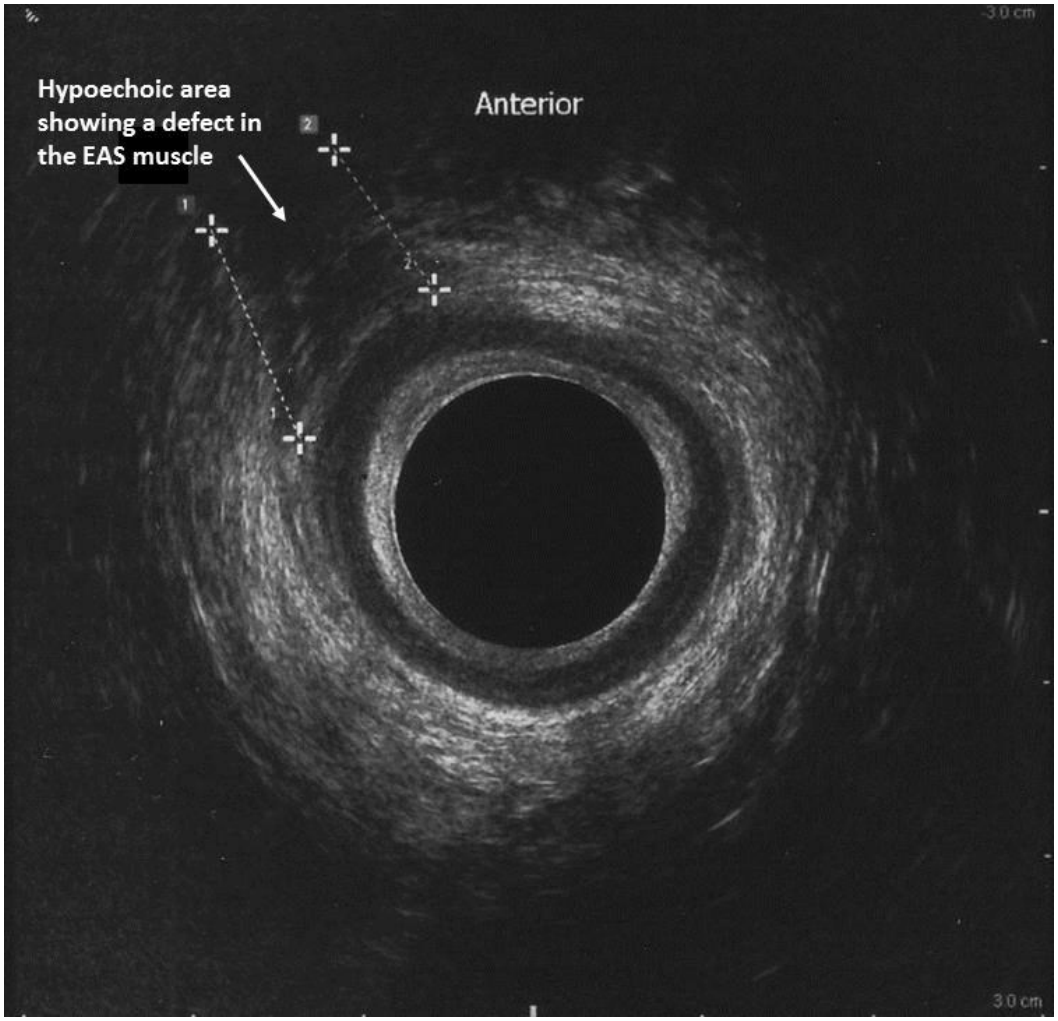


Figure 1.8 Ultrasound image showing a defect in the external anal sphincter

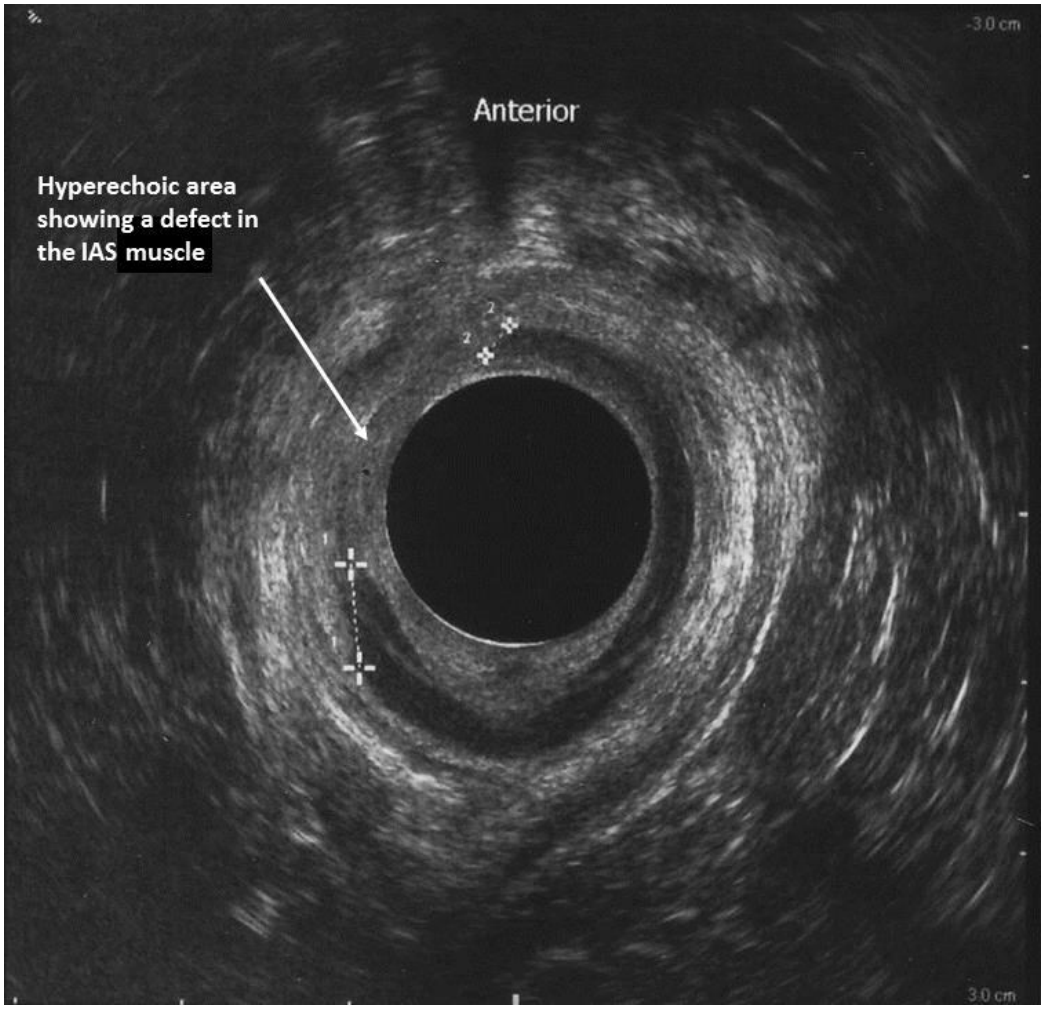


Figure 1.9 Ultrasound image of a defect in the internal anal sphincter

1.2.3 Anal manometry

Anorectal manometry is a physiological test designed to investigate the functioning of the anal canal and rectum through the measurement of anal sphincter pressures, the assessment of rectal sensation and the testing of normal anorectal reflexes. The results of the manometry test alongside other investigations can assist in the diagnosis of a variety of anorectal and pelvic floor disorders such as faecal incontinence, and obstructive defecation. The test involves insertion of a narrow balloon tipped catheter into the rectum. The catheter is usually fitted with a number of pressure sensors designed to measure anal and rectal pressure and the balloon on the end can be inflated to stimulate the rectum. The test allows the measurement of anal canal resting pressure (mainly generated by the internal anal sphincter), voluntary anal squeeze pressure (mainly generated by the external anal sphincter) and the involuntary anal squeeze pressure (generated by coughing) to assess the external anal sphincter reflex. Normal anal resting and squeeze pressures are shown in table 1.2.

Anal resting pressures

A weak anal resting pressure can indicate a weakness in the internal anal sphincter which may be the result of thinning (e.g. due to aging) or damage (e.g. as a result of surgery or a 3c or 4th degree OASIS). A weak anal resting pressure may cause symptoms of faecal leakage. A high anal resting pressure can be associated with anal fissures.

Anal squeeze pressures

A weak anal squeeze pressure can indicate a weakness in the external anal sphincter which may be the result of thinning (e.g. due to aging) or damage (e.g. as a result of surgery or a 3c or 4th degree OASIS). A weak anal squeeze may cause symptoms of faecal urgency and AI.

Table 1.2 Normal anal resting and squeeze pressures

	normal range, cm H_2O
Maximal Anal Resting Pressure	61-163
Average Maximal Anal Incremental Squeeze Pressure	50-181

The normal ranges as detailed in table 1.2 are based on those for an average person (male or female). Consequently, pressures for a pregnant or postnatal woman may be reduced due to the relaxant effects of pregnancy-related hormonal changes. There is currently no published research into squeeze pressures for pregnant women. Therefore, the use of anal manometry as a diagnostic tool to identify abnormal bowel function in women during the antenatal and postnatal period remains subjective. The RCOG acknowledge this limitation in anal manometry results and suggest it as an optional investigation in the management of women with OASIS.

1.3 Manchester Health Questionnaire

Anal incontinence (AI) is an embarrassing and distressing condition and often eliciting such information through a face-to-face discussion during a clinical consultation can be very difficult (48, 49). Self-completed questionnaires have been shown to be a more effective method in obtaining information of a sensitive nature rather than a direct question and answer approach. In a prospective study undertaken to ascertain the prevalence of AI in women undergoing tests for bladder problems, Khullar et al (1998), found 15.3% (71/465) of the women reported AI on direct questioning with the clinician, however, 26% (121/465) of the women reported this on a self-completed questionnaire (50).

There are only a few questionnaires that have been specifically designed to assess bowel function and/or its impact on QoL. In 2007, Avery et al undertook a thorough review of the scientific robustness and appropriateness of questionnaires for evaluating symptoms and the QoL impact of urinary and/or AI, vaginal and pelvic floor problems and the use of these questionnaires within research studies (51). They used the International Consultation on Incontinence Committee standardised recommendation grades for questionnaires that were based on the Oxford Centre for Evidence Based Medicine Levels of Evidence (52). Their recommendations for questionnaires for symptoms and QoL impact of AI are shown in table 1.3.1.

Table 1.3 Recommended questionnaires for AI symptoms and impact on QoL

Grade A (Highly Recommended): validity, reliability and responsiveness established with rigor.	None
Grade B (Recommended): validity and reliability established with rigor or validity, reliability and responsiveness indicated.	Fecal Incontinence QoL Scale (53) Manchester Health Questionnaire (54) Birmingham Bowel and Urinary Symptoms Questionnaire (55)
Grade C (with potential): early development, further work required and encouraged.	Wexner score (56) St. Marks score (57) Fecal Incontinence Questionnaire (58) Elderly Bowel Symptoms Questionnaire (59) Postpartum Flatal and Fecal Incontinence QoL Scale (60) Bowel Disease Questionnaire (61) Gastrointestinal QoL Index (62)

In their comprehensive review, Avery et al (2007) found no AI questionnaires that demonstrated sufficient evidence to attain grade A status (highly recommended) and only three that demonstrated validity, reliability and responsiveness to achieve grade B (recommended) (51). Therefore, for the two cohort studies undertaken within this thesis it was decided to use the Manchester Health Questionnaire (MHQ) (54) that was rated as Grade B. The MHQ was chosen as it was designed for the assessment of women only, unlike the Fecal Incontinence Scale (53) that was designed for use in both males and females, and consequently the MHQ questions were considered to be more suited for use in a study that was only involving women. The MHQ was also chosen in preference to the Birmingham Bowel and Urinary

Symptoms Questionnaire (55) as this validated questionnaire included assessment of urinary incontinence that was not under investigation in the two studies undertaken within this thesis.

The MHQ captures bowel function/symptoms experienced within the four weeks prior to completion of the questionnaire (faecal urgency, difficulty wiping, poor control of flatus, faecal incontinence) and the consequent impact on QoL reflected in nine QoL domains: General Health Perception, Incontinence Impact, Role Limitations, Physical Limitations, Social Limitations, Personal Relationships, Emotions, Sleep/Energy and Severity Measure. All of the QoL domains have more than one question to assess them and each domain is scored, whereby a lower score equates to less impact on QoL. The scoring calculation is provided in Appendix 1.2. The MHQ questions concerning bowel function are a symptom index and do not form part of the QoL score but act as a guide to symptomatology.

1.4 Specialist OASIS clinics at Birmingham Women's and Children's NHS Foundation Trust

At the hospital in which the studies included in this thesis were undertaken (Birmingham Women's and Children's NHS Foundation Trust), two specialist clinics are provided for women who have sustained an OASIS. These are provided as recommended by the RCOG Green-top guideline 'The Management of Third- and Fourth-Degree Perineal Tears; Green-top Guideline No. 29' as discussed in section 1.1. The first is a specialist multi-disciplinary postnatal clinic for women who have sustained an OASIS during their last birth. These women are reviewed at three months following the OASIS and given a clinical examination, have a discussion of how their bowel function has been since the OASIS occurred and an endoanal ultrasound scan (EAUS) is performed to check for any abnormalities of the anal sphincter muscles. The second is a specialist antenatal clinic provided for pregnant women who have previously sustained an OASIS and booked with a subsequent pregnancy at the Trust. This antenatal clinic is provided in order that these women are reviewed during their next pregnancy to offer and perform an EAUS to assess their anal sphincter integrity and to have a discussion with them about their bowel function since the OASIS occurred. Then the findings from this consultation and the EAUS are used to plan the subsequent birth mode with the woman.

Both of these clinics are run by the Trust Specialist Perineal Midwife who is the author of this thesis and who has undertaken all of the studies encompassed within. In her specialist role she is responsible for the clinical consultation regarding bowel function, physical examination and performing and interpreting the EAUS images for

the women attending these clinics. She is also responsible for counselling the women with previous OASIS on the mode of subsequent birth which are in line with the RCOG Green-top guideline recommendations as outlined in section 1.1.3 (with the exception of anal manometry as discussed in section 1.2.3). Women are advised on the recommended mode of birth based on the RCOG Green-top guidelines but supported in their decision on mode of birth should it differ from the RCOG recommendations.

1.5 Thesis rationale and overview

This thesis has been undertaken to investigate the effect of subsequent birth and its mode for women with a previous OASIS. The author of this thesis has been undertaking the Specialist Perineal Midwife role (see section 1.4), since 2004. A question that has been consistently asked by women who have sustained a previous OASIS and attending for their postnatal clinical review is 'what is the most suitable mode of a subsequent birth?' It is clear this has been a source of major concern and upset/distress for numerous of these women. As discussed in section 1.1.6, despite current available evidence being limited and of low level, it would suggest that a subsequent vaginal birth is suitable for women with normal bowel function and normal sphincter anatomy on EAUS and/or normal anal manometry. The 13 years specialist clinical experience of the author also concurred with this finding and led to a research hypothesis that for women with a previous OASIS who had normal bowel function and normal sphincter anatomy a subsequent vaginal birth would be unlikely to have an effect on normal bowel function or have a negative impact on QoL. The intention was that findings from the study would provide better evidence than is currently available and that is recognised as needed, to assist clinicians and women with previous OASIS when considering and planning mode of birth during a subsequent pregnancy.

This work in this thesis consists of three studies. The first study is a systematic review and meta-analysis of the impact of a subsequent birth and its mode on bowel function and/or QoL for women with a previous OASIS. The second study is a long-term postal questionnaire-based cohort study to assess the natural history of OASIS

and its relationship with long-term bowel function and related QoL and to identify any significant independent characteristics that may contribute to longer term bowel symptoms or impact on QoL, including subsequent birth. The third study is a prospective observational cohort study to assess the impact of a subsequent birth and its mode on change in bowel function and QoL in newly pregnant women who had previously sustained OASIS.

.

2 A SYSTEMATIC REVIEW AND META-ANALYSIS OF THE IMPACT OF SUBSEQUENT BIRTH AND ITS MODE FOR WOMEN WITH PREVIOUS OBSTETRIC ANAL SPHINCTER INJURY.[↗]

2.1 Introduction

Obstetric anal sphincter injuries (OASIS) are serious complications of vaginal birth with a reported UK incidence of 5.9% (63). They are recognised to be a major risk factor of anal incontinence (AI) resulting in concern amongst some women when considering the mode of birth for a subsequent pregnancy after having sustained an OASIS. Recent UK data demonstrate a steadily rising incidence of this type of trauma over the past decade, possibly due to increased awareness and improved methods of detection (14) . Using an average prevalence of 5%, it is estimated that 30,000 women in the UK sustain OASIS annually. Even though risk of AI is substantially increased after OASIS most women with this injury have no bowel problems. For these women and in the absence of an obvious sphincter defect on ultrasound, the Royal College of Obstetricians and Gynaecologists' (RCOG), recommends discussion and consideration of all modes of birth , based on limited, low level 4 evidence (40). Indeed, data show that, prior to consideration of AI symptoms, over 60% of women with previous OASIS would prefer a subsequent vaginal birth (64).

[↗] The work in this chapter has been published as Webb SS, Yates D, Manresa M, Parsons M, MacArthur C, Ismail KMK. Impact of subsequent birth and delivery mode for women with previous OASIS: systematic review and meta-analysis. International Urogynecology Journal. 2017 ; 28(4) : 507-14

Therefore, the majority of women seem to be keen to avoid unnecessary major surgical intervention, such as caesarean section, although a significant number are still cautious to pursue another vaginal birth that could result in further damage to the pelvic floor and long-term AI. This systematic review aims to assess currently available evidence to guide women with previous clinically diagnosed OASIS in making an informed choice about subsequent birth and its mode.

2.2 Methods

A protocol using widely recommended methods for systematic reviews of observational studies was developed and registered with PROSPERO International prospective register of systematic reviews (65, 66). The PRISMA statement and checklist were followed throughout review preparation, undertaking and reporting (Appendix 3.1).

2.2.1 Sources

MEDLINE, EMBASE, CINAHL and AMED databases were searched electronically from inception to February 2016. A combination of medical subject headings (MeSHs), to encompass both bowel function and quality of life, keywords and word variants using Boolean operators 'OR' and 'AND' to capture relevant text citations were used. Search strategies were adapted for each database (Appendix 3.2). The term of 'subsequent birth' was not included in the original search to reduce the risk of limiting access to all possibly relevant articles. In addition, reference lists of relevant articles were manually searched to identify papers not captured by electronic

searches. The search focused on capturing any Randomised Controlled Trials (RCTs) or Non-Randomised Studies (NRSs) studies reporting the impact of a subsequent birth on bowel function and/or quality of life for women with previous OASIS. Case series and case reports were excluded. Conference papers and abstracts were included if they contained sufficient information regarding study design and outcome data. No language restrictions were applied but the search was limited to human studies. The search strategies were developed by two reviewers and a database of all abstracts of citations was compiled.

2.2.2 Study selection and data extraction

Studies were selected in a three stage process. Firstly, each title and abstract were assessed by two reviewers and full articles of all references that were likely to fulfil predefined criteria were obtained. These articles were then assessed by two independent reviewers, against pre-designed inclusion/exclusion criteria with any discrepancies referred to a third party for final decision. Studies were included if they gave information with supporting statistical evidence on AI and/or QoL for women with previous OASIS undergoing a subsequent birth.

Data were extracted on study quality, participants' characteristics and impact of subsequent birth and mode, on bowel function, including de novo symptoms or changes in pre-existing symptoms, and/or QoL using a pre-designed data capture form. Data extraction was performed by two reviewers, with assistance from a third reviewer should a discrepancy occur.

The primary outcome was the impact of having a subsequent birth on AI and/or QoL for women with previous OASIS. Sub-analyses were planned on the impact of a subsequent birth versus no subsequent birth (irrespective of mode) on AI and/or QoL and the impact of a subsequent vaginal birth versus subsequent caesarean section on AI and/or QoL. The definition of AI encompassed the ICS recognised definition of AI that is involuntary loss of flatus, liquid or solid faeces, and also faecal urgency (67). When extracting data it was noted whether the studies considered each of these elements in isolation or as composites. Whenever possible, data were extracted to compute 2 x 2 tables where women with previous OASIS had reported the impact of the subsequent birth on AI and/or QoL, through either questionnaires or interviews.

2.2.3 Study quality assessment

Risk bias and the quality of the included cohort studies were assessed by using the Joanna Briggs Institute Prevalence Critical Appraisal Tool (68) (Table 2.1). Case control studies were quality assessed using the Newcastle-Ottawa Quality Assessment Scale (69) (Table 2.2). Quality assessment was then used to assess the methodological adequacies of the included studies and assist with interpretation of meta-analysis findings and possible bias resultant from study heterogeneity.

Table 2.1 Quality assessment criteria for cohort NRSs using Joanna Briggs Institute Prevalence Critical Appraisal Tool

10 suggested criteria	**Interpretation for this systematic review**
Sample representativeness of target population?	Previous OASIS categorised
Recruited in appropriate way?	Consecutive recruitment
Adequate sample size?	Adequate sample size calculation undertaken
Study subjects and setting described in detail?	Study subjects and setting described in detail
Is the data analysis conducted with sufficient coverage of the identified sample?	Adequate discussion/description of non-responders
Were objective, standard criteria used for measurement of the condition?	Validated questionnaire used
Was the condition measured reliably?	Prospective assessment of condition
Was there appropriate statistical analysis?	Appropriate statistical analysis provided
Are all important confounding characteristics/subgroups/differences identified and accounted for?	Parity of women clearly identifiable at onset
Were subpopulations identified using objective criteria	Parity of women with condition

Table 2.2 Quality assessment criteria for case control NRSs using Newcastle-Ottawa Quality Assessment Scale

8 suggested criteria	Interpretation for this systematic review
Selection	**Selection**
Is the case definition adequate?	Previous OASIS categorised
Representativeness of the cases?	Consecutive recruitment
Selection of controls	Consecutive selection of controls
Definition of controls	No OASIS
Comparability	**Comparability**
Comparability of cases and controls on the basis of the design or analysis	Study control for previous OASIS/matched on parity/age/mode
Exposure	**Exposure**
Ascertainment of exposure	Validated questionnaire used
Same method of ascertainment for cases and controls	Same method of ascertainment for cases and controls
Non-response rate	same rate for both groups

2.2.4 Data synthesis

RevMan 5.2 was used for statistical analysis (70). A random-effects model was used because of the high likelihood of clinical and statistical heterogeneity. Meta-analysis was performed if two or more eligible studies provided comparable data. All other eligible studies were analyzed descriptively. Dichotomous data are presented as summary odds ratios with 95% confidence intervals. Continuous data are presented as standardized mean differences. Statistical heterogeneity in the meta-analysis was assessed by using the I^2 statistic and any value >25% was considered significant and investigated further with sensitivity analysis of excluding studies of markedly different study design/dataset (71).

2.3 Results

27 Non Randomised Studies (NRSs) from nine countries were included (25 Cohort; 2 Case Control) (Appendix 2.3) of which 14 cohort NRSs were included for quantitative synthesis by meta-analysis (Figure 2.1) (Appendix 2.4). No Randomised Controlled Trials (RCTs) or relevant systematic reviews were identified.

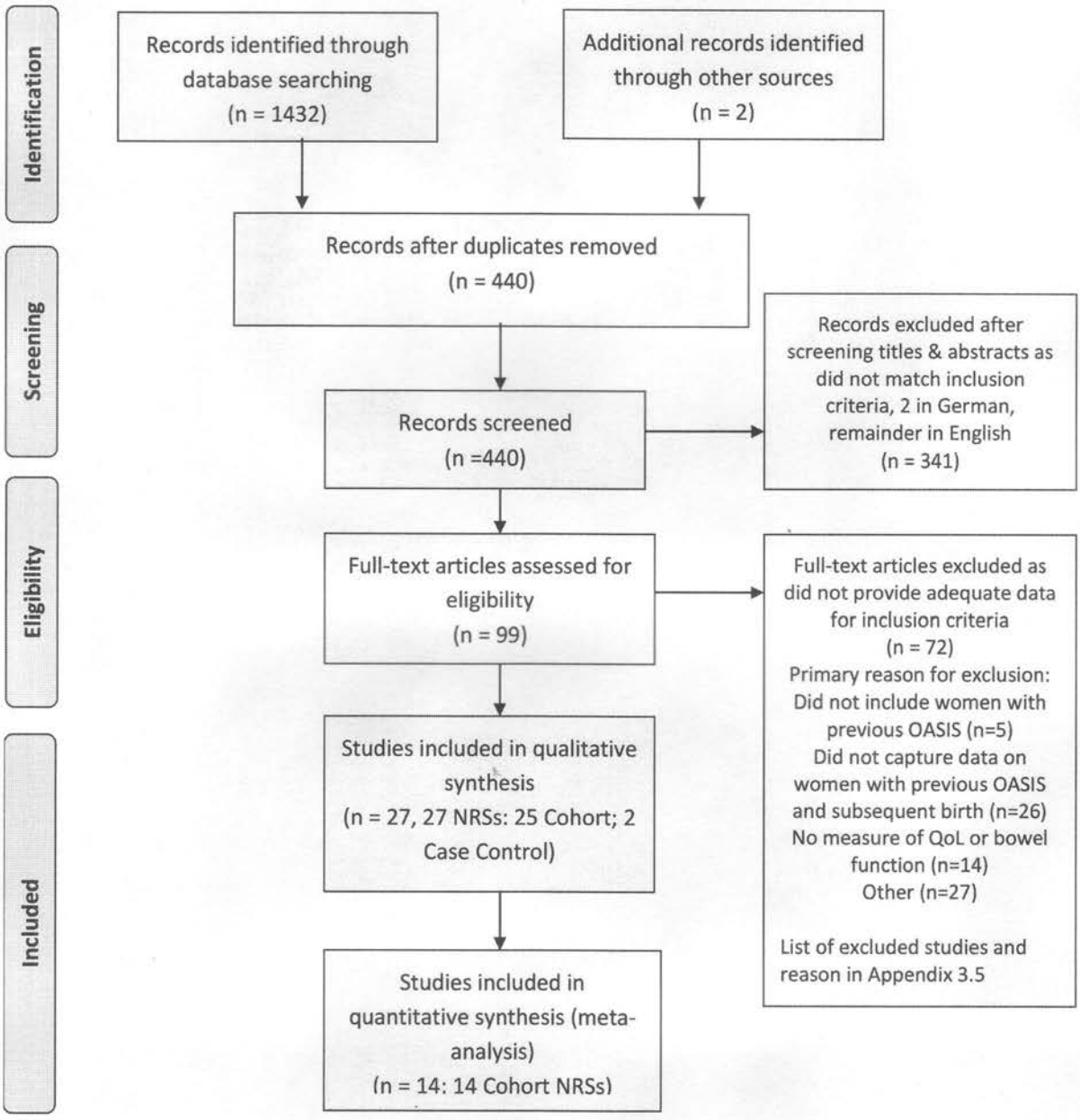


Figure 2.1 PRISMA 2009 Flow chart

Study quality assessment of all included cohort and case control studies revealed deficiencies in many methodological areas. For the cohort NRSs, no studies met all ten quality criteria (Figure 2.2).

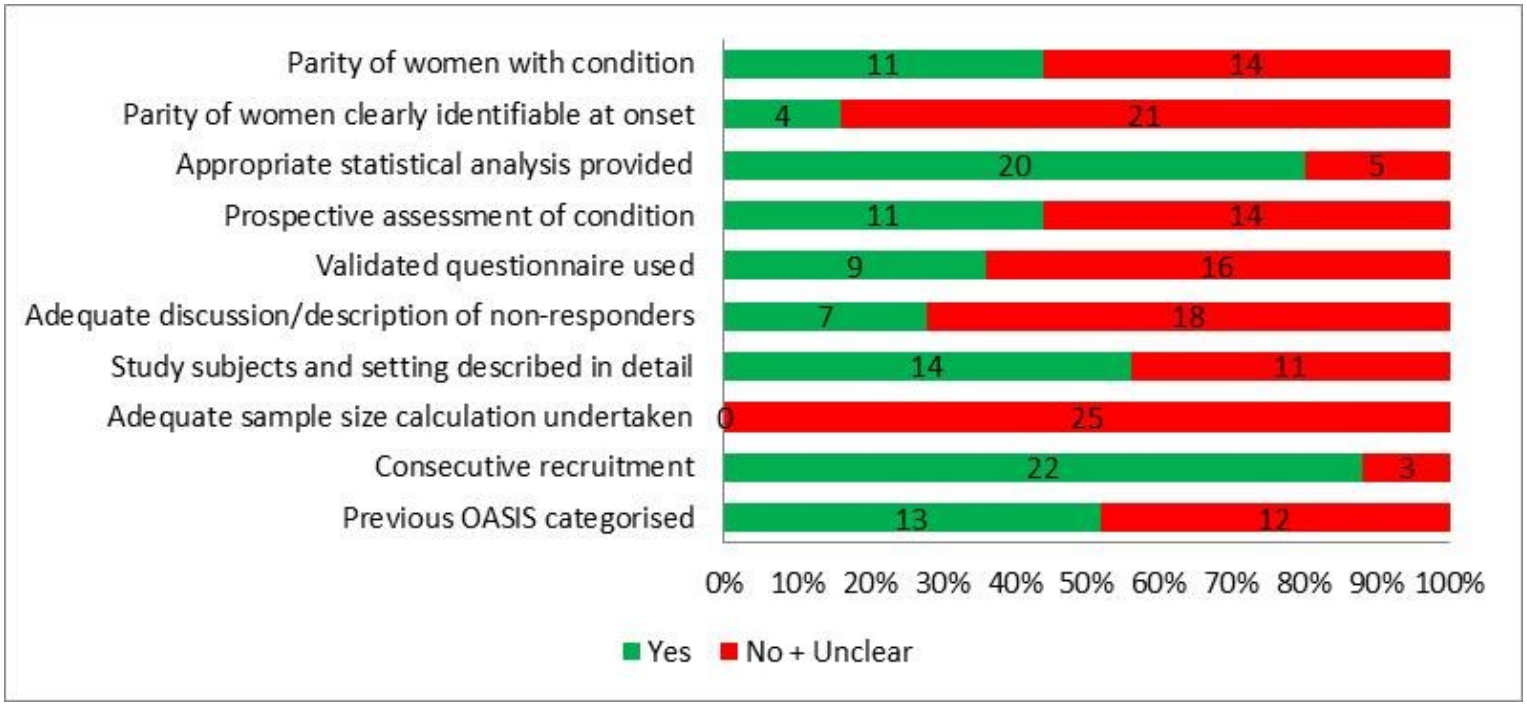


Figure 2.2 Quality assessment criteria for 25 included cohort NRSs using Joanna Briggs Institute Prevalence Critical Appraisal Tool

Only one study (3.84%) met eight criteria, the remainder fulfilled seven or less with 15 studies (60%) meeting ≤50% of the quality criteria. Neither of the two case control studies met all nine criteria (Table 2.3). No studies were excluded from the systematic review for failure to fulfil the quality criteria.

Table 2.3 Quality assessment criteria for two included case control NRSs using Newcastle-Ottawa Quality Assessment Scale

8 criteria	Naidu et al	Wagenius et al
Selection		
Previous OASIS categorised		*
Consecutive recruitment		*
Consecutive selection of controls		*
No OASIS	*	*
Comparability		
Study control for previous OASIS/matched on parity/age/mode	*	**
Exposure		
Validated questionnaire used		
Same method of ascertainment for cases and controls	*	*
Same rate for both groups		
Total score (out of possible 9)	3/9	7/9

In relation to the primary objective, 13 of the total 27 studies which satisfied inclusion criteria, (48.2%) were undertaken primarily to assess the impact of a subsequent birth for women with previous OASIS (Appendix 2.4). From all 27 included studies a total of 3297 women were followed up after a primary OASIS, however, data regarding the impact of subsequent birth on AI and/or QoL were only available for 1781 women (54%). Due to the structure of the questionnaires and reporting methods for multiple symptoms, data on relevant outcomes were only available for meta-analysis on 997 (977/1781; 55.9%) of these women, in 14 studies. Studies that could not be meta-analysed are individually described. Of the 27 included studies, 12 studies (44.4%) considered the impact of a subsequent birth on a woman's QoL.

The use of validated measurement tools was reported in 37.1% of the studies.

Only two of the included studies (7.4%), provided details about the required sample sizes needed to achieve adequate powering of calculations, however, these were not achieved in either study due to high attrition rates.

Fifteen (55.5%) of the included studies used data for women who sustained and had OASIS repaired before the first edition of the RCOG green top guidelines in July 2001 recommending that standardised classification and repair management be introduced.

2.3.1 Subsequent birth vs no-subsequent birth (irrespective of mode) for women with previous OASIS – impact on AI.

Meta-analysis of five cohort NRSs (72-76), did not demonstrate a significant difference in reported AI in women with previous OASIS who had a subsequent birth, irrespective of mode, compared to those who did not (562 women; OR 1.25; 95% CI 0.73-2.15; I^2 = 36%; Figure 2.3). Unlike all other studies included in this meta-analysis, Nordenstam et al (76) had a primary study objective of the natural progression of AI following childbirth not specifically for women with previous OASIS. Inclusion of this study resulted in an I^2 value of 36%. The meta-analysis was therefore repeated following exclusion of this study, however, this still did not demonstrate a significant difference (532 women; OR 1.36; CI 0.84-2.19; I^2 = 25%).

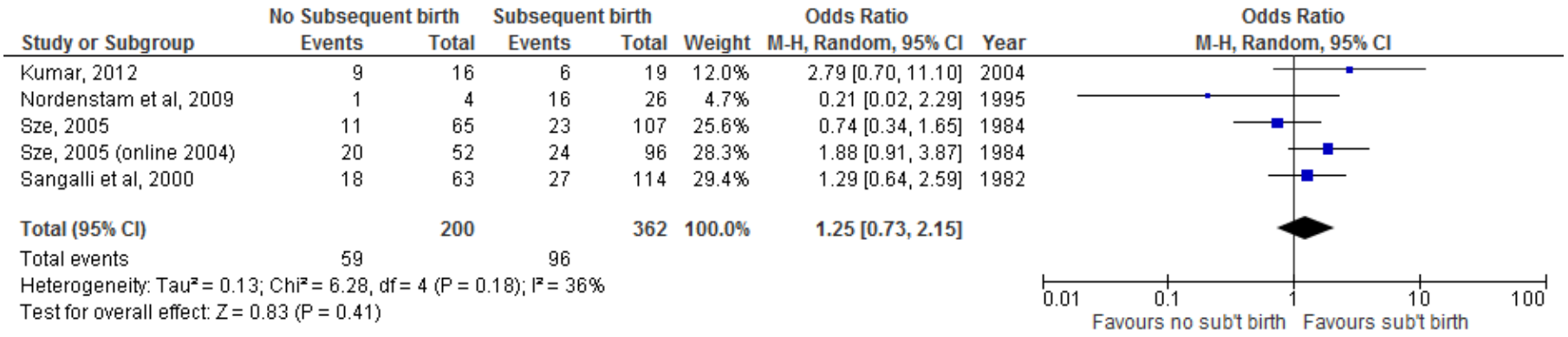


Figure 2.3 Reported incidence of AI in women with previous OASIS: no subsequent birth versus subsequent birth

Of the two studies by Sze (72, 74) , both undertaken in the USA, one demonstrated outcomes favouring subsequent vaginal birth for women with previous 4th degree OASIS (OR 1.88, 95% CI 0.91-3.87) compared to the other favouring no subsequent vaginal birth for women with the lower category (3c) OASIS, however, neither reached statistical significance (OR 0.74, 95% CI 0.34-1.65).

Several studies that reported data relevant to this comparison but could not be included in meta-analysis provided contradictory information. In a retrospective cohort study of 125 women with matched controls, De Leeuw et al (77) , reported that for women with previous OASIS there was no association between AI and having a subsequent vaginal birth or not (41% vs 39% respectively) (OR 2.32; 95% CI 0.85-6.33; p=0.10). A retrospective follow up NRS (mean 27.5 years ± 2.4) of 99 women with OASIS from their first birth by Huebner et al (78), also found no association between parity irrespective of mode and anal incontinence of either liquid/solid stool (OR 1.69; 95% CI 0.58-4.97; p=0.335) or flatus (OR 2.25; 95% CI 0.94-5.41; p=0.067). Likewise, in their study of women with OASIS and matched controls (mean follow up 22.2 years), Soerensen et al (79), found no association between long-term AI and having a subsequent birth in women with a 3c or 4th degree OASIS. While a retrospective cohort study by Sangalli et al (75), reported that subsequent vaginal birth in women who previously sustained 3rd degree OASIS (n=80) was associated with a significant decrease in severity of AI (*p*=0.02) whereas for women with previous 4th degree OASIS (n=34), subsequent vaginal birth was associated with an increased risk of severe incontinence (*p*=0.042). A similar study by Bek & Lauberg (80), found a significant association between transient AI in

women directly after sustaining primary 'complete' OASIS and permanent AI after a subsequent vaginal birth (OR 8.7; 95% CI 1.9-39; *p*=0.05), however the study sample size was small (n=56). Reid et al (81), also found that having a subsequent birth was significantly associated with symptoms of AI at 3 years following primary OASIS (*p*=0.012). Similarly, in a small study (N=117) Poen et al (82), demonstrated a significantly higher incidence of reported symptoms of AI in women with subsequent birth versus those without (RR 1.6; 95%CI 1.1-2.5; *p*=0.025) (mean follow up period was 4.7 years; range 0.8-11.3). Visscher et al (83), found that AI was increased in women with subsequent birth relative to those without (p=0.008) but this was a very small study that excluded all women who were asymptomatic following their first OASIS.

Three studies provided data on AI symptoms in relation to the total number of subsequent births following OASIS (72, 74, 75) . Meta-analysis of these did not demonstrate a difference in reported AI related to one, compared with two or more subsequent vaginal births for any category of OASIS (two studies, 210 women; OR 0.88; 95% CI 0.40-1.94; I^2 = 19%; Figure 2.4), or for women with a previous 4th degree OASIS (two studies, 130 women; OR 0.94; 95% CI 0.39-2.31; I^2 = 12%; Figure 2.5).

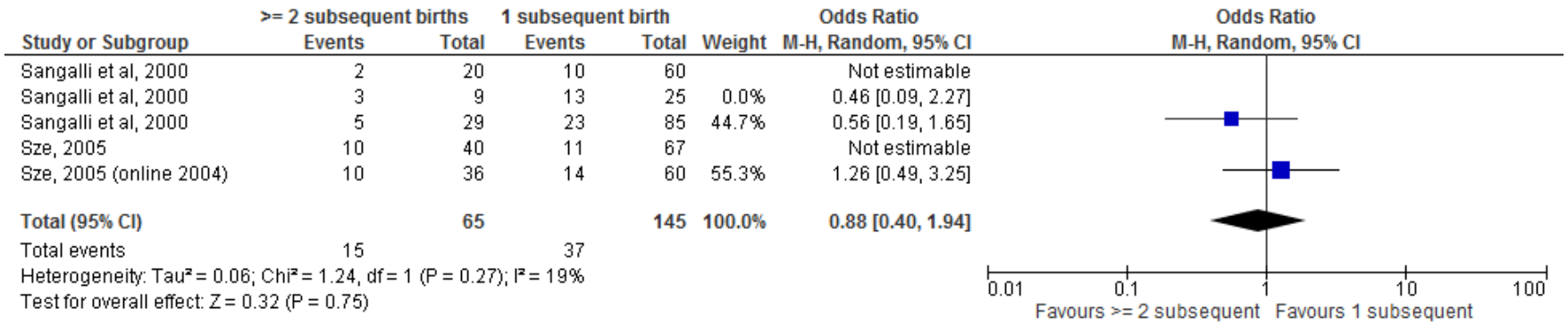


Figure 2.4 Incidence of AI in women with previous OASIS: ≥ 2 subsequent births versus 1 subsequent birth.

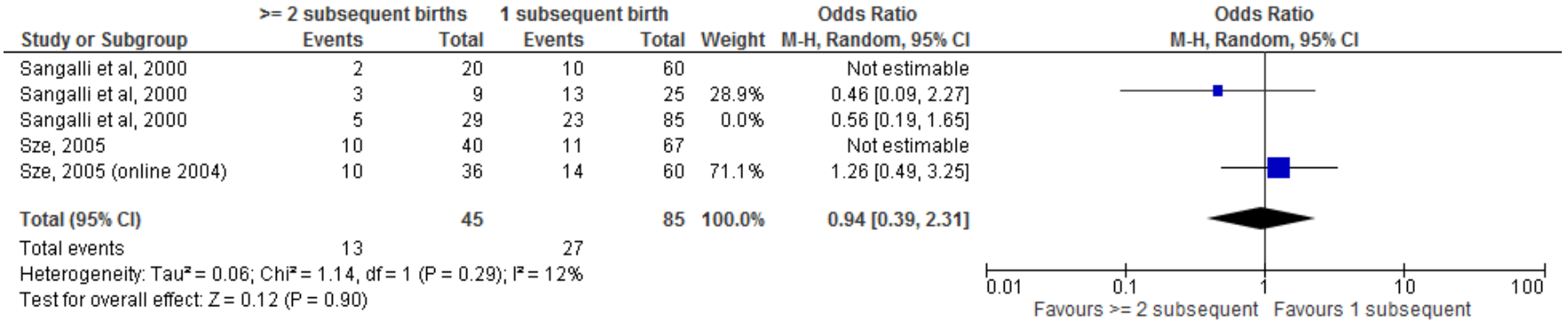


Figure 2.5 Incidence of AI in women with previous 4th degree OASIS: ≥ 2 subsequent births versus 1 subsequent birth.

Regarding change in reported AI, meta-analysis of eight cohort NRSs (76, 80, 84-89), demonstrated that there was no significant change in reported AI symptoms in women with previous OASIS prior to and following their subsequent birth irrespective of mode (438 women; OR 1.20; 95% CI 0.65-2.20; I^2 = 39%; Figure 2.6). Unlike all other studies included in the meta-analysis, Tetzschner et al (86) and Bondili et al (88) reported findings on women with subsequent elective caesarean section and inclusion of these two studies in the meta-analysis resulted in an I^2 value of 34%. A repeat meta-analysis without the inclusion of these studies still did not demonstrate a significant worsening in AI for women with previous OASIS following a subsequent vaginal birth (161 women; OR of 1.69; CI 0.89-3.22; I^2 = 0%).

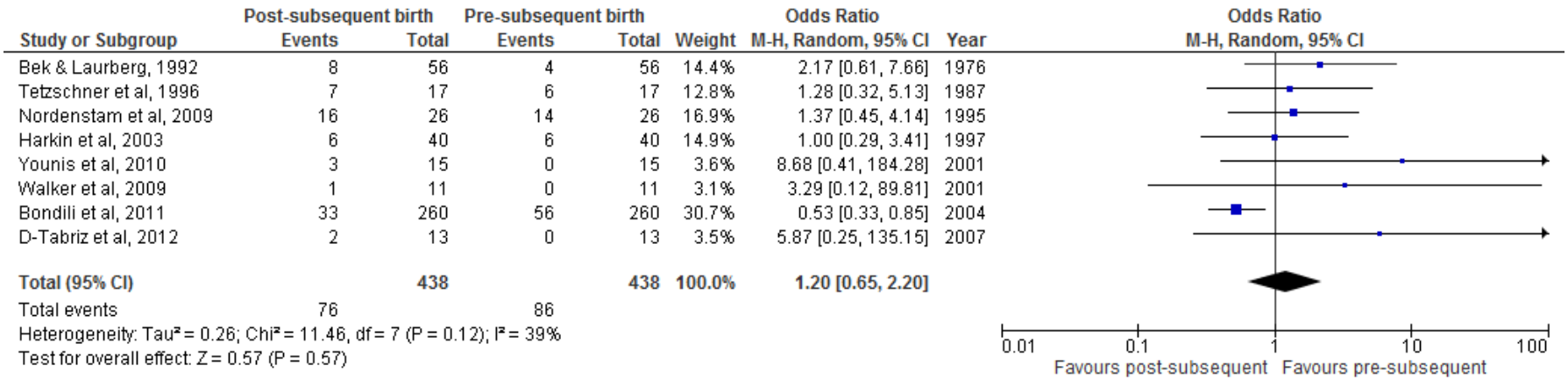


Figure 2.6 Reported incidence of AI in women with previous OASIS: Pre- versus post-subsequent birth

With regard to individual studies, An et al (90) showed that in her sample of 67 women with previous OASIS, 82% reported AI symptoms to be the same or improved following a subsequent birth and concluded that low AI measurement scores pre-subsequent birth were a significant predictor of normal continence post-subsequent birth (p=0.0002).

2.3.2 Subsequent birth vs no-subsequent birth (irrespective of mode) for women with previous OASIS – impact on QoL.

QoL was studied in only one small case control study of women who sustained recurrent OASIS in the subsequent birth (cases n= 34) compared to women who did not, matched for age and ethnicity (controls n=34), showing no change to QoL for women at 12 weeks postpartum compared to antenatal parameters, nor between the two groups (Naidu et al (91)).

2.3.3 Subsequent vaginal birth vs subsequent caesarean section for women with previous OASIS – impact on AI.

Three cohort NRSs were meta-analysed for mode of subsequent birth (86, 92, 93), which did not demonstrate any difference in de novo AI or worsening of symptoms in women with previous OASIS following subsequent vaginal birth relative to subsequent caesarean section (three studies, 199 women; OR 0.63; 95% CI 0.21-1.88; I^2 = 0%; Figure 2.7).

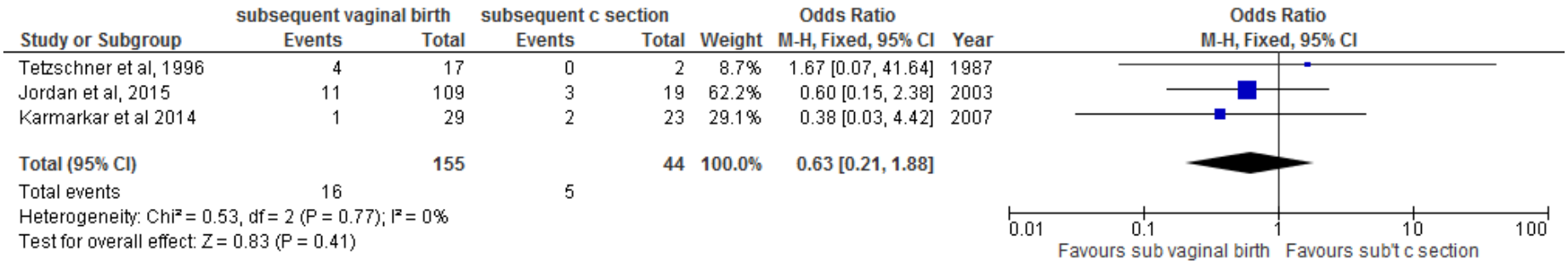


Figure 2.7 Incidence of worsening or de novo symptoms of AI in women with previous OASIS: subsequent vaginal birth versus subsequent caesarean section

Similar to other outcomes, individual studies produced mixed findings. In a prospective cohort study after primary sphincter repair, Reid et al (81), found that at three year follow-up AI symptoms were more frequent in women with subsequent caesarean section (5/92), however, they attributed this to the fact that symptomatic women were offered elective caesarean section.

Naidu et al (91), Fitzpatrick et al (94) and Jorden et al (95), found no worsening of AI symptoms for women having whatever mode of subsequent birth they were recommended by their clinician. Scheer et al (44), using a validated questionnaire, demonstrated an improvement in all symptoms of AI except solid incontinence, after subsequent vaginal birth, however, again, the study only included women who underwent their recommended mode of subsequent birth and was very small (n=35).

2.3.4 Subsequent vaginal birth vs subsequent caesarean section for women with previous OASIS – impact on QoL.

Scheer et al also studied QoL and found a significant negative impact on three domains post birth; incontinence impact (p=0.012), emotions (p=0.003) and severity measures (p=0.032), for women (n=9) having subsequent recommended caesarean section (due to the substantial compromised anal function), compared to those undergoing a recommended vaginal birth.

2.3.5 Sub-analyses with studies using data from women with a subsequent birth after having sustained primary OASIS from 2003 onwards

To allow time for RCOG green-top guideline evidence based recommendations to be embedded into clinical practice (15), a sub analysis of studies with subsequent birth data from women having sustained their primary OASIS from 2003 onwards was undertaken. Meta-analysis for the impact on AI of subsequent birth vs no-subsequent birth (irrespective of mode) for women with previous OASIS was not possible as only one study, Kumar et al (2012) (73) was suitable for inclusion (Figure 2.8).

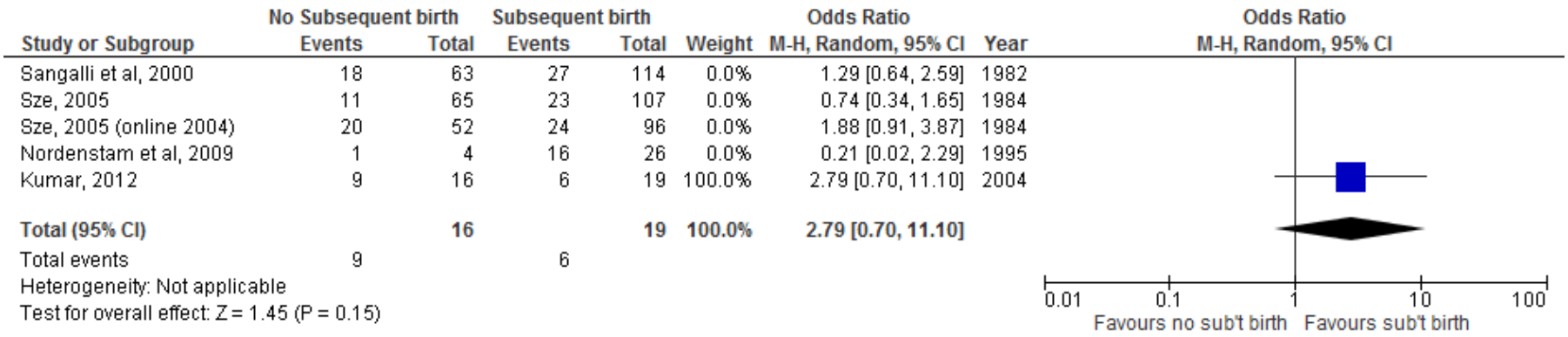


Figure 2.8 Reported incidence of AI in women with previous OASIS sustained 2003 onwards: no subsequent birth versus subsequent birth

Regarding change in reported AI, meta-analysis of two cohort NRSs (85, 88), demonstrated that there was no significant change in reported AI symptoms in women with previous OASIS prior to and following their subsequent birth irrespective of mode (273 women; OR 1.05; 95% CI 0.12- 8.89; I^2 = 55%; Figure 2.9). As only two studies were suitable for inclusion (having collected data on women who had sustained OASIS post-2003), it was not possible to investigate the significant statistical heterogeneity demonstrated any further by removal of either of the studies despite their being a marked difference in each of their primary study aim and design.

Study or Subgroup	Post-subsequent birth Events	Total	Pre-subsequent birth Events	Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
Bek & Laurberg, 1992	8	56	4	56	0.0%	2.17 [0.61, 7.66]	1976
Tetzschner et al, 1996	7	17	6	17		Not estimable	1987
Nordenstam et al, 2009	14	26	16	26	0.0%	0.73 [0.24, 2.20]	1995
Harkin et al, 2003	6	40	6	40	0.0%	1.00 [0.29, 3.41]	1997
Walker et al, 2009	1	11	0	11	0.0%	3.29 [0.12, 89.81]	2001
Younis et al, 2010	3	15	0	15	0.0%	8.68 [0.41, 184.28]	2001
Bondili et al, 2011	33	260	56	260	71.5%	0.53 [0.33, 0.85]	2004
D-Tabriz et al, 2012	2	13	0	13	28.5%	5.87 [0.25, 135.15]	2007
Total (95% CI)		**273**		**273**	**100.0%**	**1.05 [0.12, 8.89]**	
Total events	35		56				

Heterogeneity: $Tau^2 = 1.60$; $Chi^2 = 2.22$, df = 1 (P = 0.14); $I^2 = 55\%$

Test for overall effect: Z = 0.05 (P = 0.96)

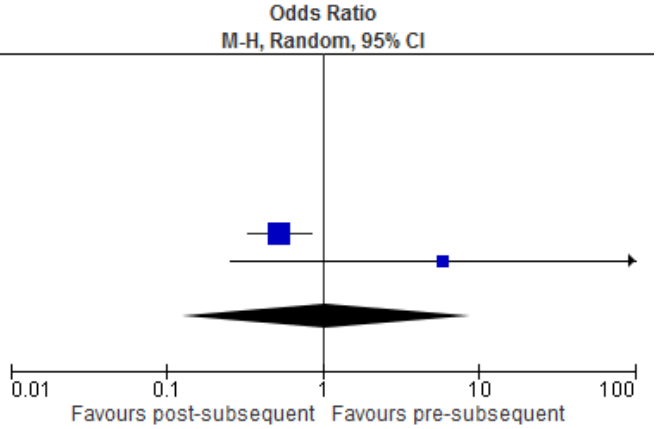


Figure 2.9. Reported incidence of AI in women with previous OASIS sustained 2003 onwards: pre- versus post-subsequent birth

Regarding change in reported AI related to mode of subsequent birth, meta-analysis of two cohort NRSs (92, 93) , demonstrated that there was no significant change in reported AI symptoms in women with previous OASIS prior to and following their subsequent birth irrespective of mode (136 women; OR 0.53; 95% CI 0.16- 1.78; I^2 = 0%; Figure 2.10).

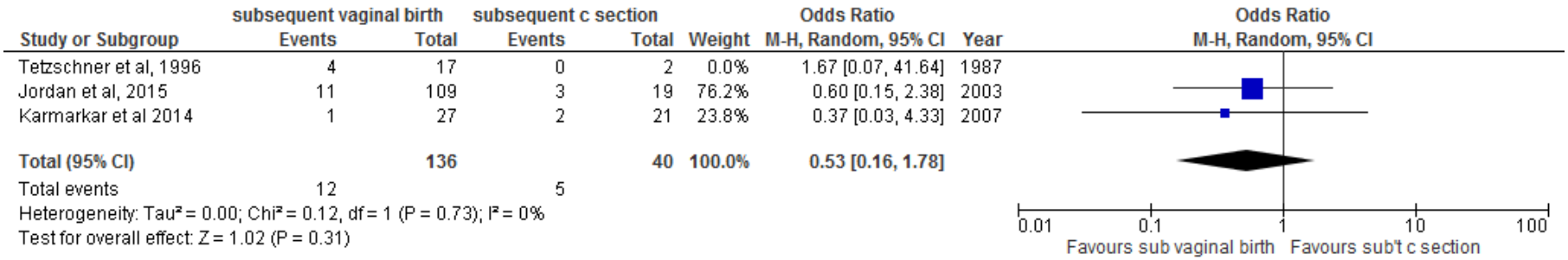


Figure 2.10. Incidence of worsening of or de novo symptoms of AI in women with previous OASIS sustained 2003 onwards: subsequent vaginal birth versus subsequent caesarean section

2.4 Discussion

2.4.1 Main findings

This systematic review summarises available evidence regarding impact of subsequent birth for women with previous history of OASIS on AI and/or QoL. As no RCTs were identified, this is based on data from 27 cohort and case control NRSs, across nine countries, predominantly with methodological inadequacies (data provided for 1781 of the 3297 women where data relating to subsequent births following OASIS were available) (44, 72-76, 79-82, 84-87, 89-92, 96-103).

Meta-analysis did not demonstrate a difference in AI in women with previous OASIS who had a subsequent birth compared to those who did not (five studies; 562 women); or a change in AI in women with previous OASIS prior to and following subsequent birth irrespective of mode (eight studies; 438 women); or a difference in de novo AI or worsening symptoms in women with previous OASIS following subsequent vaginal birth compared to subsequent caesarean section (four studies; 211 women).

Despite QoL being an important indicator for women with previous OASIS when deciding on future pregnancy and mode, research in this area was limited (12 studies, 912 women) and no data were suitable for meta-analysis due to differences in outcome reporting between studies.

2.4.2 Strengths and Limitations

The several strengths to this systematic review include rigorous searching, study selection, quality appraisal and data extraction methodology. The term of 'subsequent birth' was not included in the original search to reduce the risk of limiting access to all possibly relevant articles. Also, not restricting NRSs enabled all possible studies to be included.

The main limitation of the review findings arises from both the quality and heterogeneity of included individual studies on which they are based, with the majority of studies not looking at symptom severity and of small sample sizes. All studies satisfying inclusion criteria were NRSs, 14 (52%) not conducted with the primary intention of investigating impact of subsequent birth on AI and/or QoL for women with previous OASIS. Only 14, of the included studies, reported data allowing inclusion in meta-analyses. Consequently, risk that findings from meta-analysis of NRSs are subject to over exaggeration of the tested intervention (i.e., subsequent birth or its mode) due to methodological biases must be acknowledged (104). However, lack of difference found from meta-analyses undertaken mitigates this potential risk. Data on confounding characteristics was also limited in many of the studies and must be taken into account in future research. Another consideration is improvement in OASIS recognition and repair. Structured training, use of recommended suture materials and repair techniques are associated with good clinical outcomes (42, 105, 106). Attention to the above was driven by the RCOG Green-top guideline first published in 2001 (15). Consequently data from women delivered prior to these recommendations (55.5% of included NRSs), may not be representative of those in centres where recommended interventions for OASIS

assessment and repair have been implemented. A sub analysis of studies with data from women having a subsequent birth after 2003 (to allow time for RCOG evidence based recommendations to be embedded in clinical practice), limited the number of studies eligible for inclusion and when meta-analysis was still possible, did not show any differences in findings. However, some of these results should be interpreted with caution due to evidence of significant statistical heterogeneity. Nevertheless, due to lack of evidence of universal adoption of this practice and increasing mobility of women between units and countries, results of this review remain relevant. Further sub-analysis to assess impact of suture material, repair method, follow-up on clinical outcomes would have complemented this review, however, data is not readily available in the included studies.

2.4.3 Interpretation of findings

OASIS recognition and primary repair immediately following birth has improved (14), moreover, sustaining OASIS has not been demonstrated as a characteristic deterring women from having subsequent pregnancies (21). The main focus for clinicians is helping women choose the optimal mode of subsequent birth. Clinical experience suggests there is wide variation between individual women with regard to their choice of mode of subsequent birth. Some women are prepared to pursue another vaginal birth despite evidence suggesting that risk of an OASIS in a subsequent vaginal birth is greater than for women with no previous history of OASIS (78), while other women request a caesarean section irrespective of health practitioner advice. Interestingly, the studies by Bondili et al (88) and Nordenstam et al (76), found improvements in AI in symptomatic women recommended to undergo

subsequent elective caesarean section. This improvement could be influenced by achieving the desired mode of birth, learning to cope with/adapt to symptoms of AI in the longer term or actual improvement because of management interventions like dietary changes or physiotherapy. It is important to highlight the difference in follow up period between these two studies - six months and ten years respectively. Although these findings remain a matter of debate, they demonstrate the psychological complexity of pregnancy and giving birth and that OASIS and its long-term complications cannot be considered in isolation. It is, therefore, interesting that this review highlights that over half of the research suitable for inclusion concentrates on *occurrence* of AI for women with OASIS undergoing a subsequent pregnancy and birth, but not its severity or impact on QoL.

Women may wish to pursue their desired mode of subsequent birth, however, pregnancy and childbirth is a dynamic process with unpredictable events necessitating unplanned interventions. The majority of included studies excluded women who did not obtain their planned mode of subsequent birth (through maternal choice or clinical need), or had a subsequent caesarean section. This affects representativeness as AI may be a consequence of other characteristics related to pregnancy and labour such as pudendal neuropathy, prolonged labour, instrumental delivery, or even pregnancy itself.

The current RCOG guideline (40) acknowledges that the level of evidence supporting their recommendations regarding mode of subsequent birth for women with previous OASIS is low (level 4). However, in our opinion, this review clearly

demonstrates that current evidence is substantially limited to provide any meaningful guidance.

It also highlights, as there are few studies involving women assessed and repaired using 2001 RCOG recommendations, that there is currently no literature reporting long-term outcomes on bowel function and quality of life for these women who undergo a subsequent birth. This calls for urgent collaborative prospective work to generate the required evidence to inform practice.

2.5 Conclusion

This is the first systematic review on impact of subsequent birth and its mode on AI and/or QoL for women with previous OASIS. Due to the poor methodological quality and overall heterogeneity of included studies it is not possible to determine the optimal mode of subsequent births for all women with previous OASIS and therefore better data are needed.

2.5.1 Practical recommendations

In the absence of higher quality evidence this systematic review and meta-analysis would support current recommendation of a subsequent vaginal birth for women with previous OASIS who demonstrate no AI symptoms or sphincter defects. However, evidence is urgently needed to support or refute the practice of recommending elective caesarean section for symptomatic women or those with ultrasonographic anal sphincter abnormalities.

2.5.2 Research recommendations

Findings from this review support the RCOG guideline (40) recommendation for further research. If an RCT to assess the impact of mode of subsequent birth following OASIS on both AI and QoL was deemed acceptable by women, such a trial will need to be multicentre or international to ensure timely conclusion without compromising its power to address important outcomes. A more immediate option would be a well conducted, appropriately sized prospective cohort study of women with previous OASIS undergoing subsequent birth, with primary objectives of assessment of anal function, QoL and sphincter anatomy both before and after the intervention with on-going follow up.

3 LONG-TERM BOWEL FUNCTION AND QUALITY OF LIFE IN WOMEN WHO SUSTAIN OASIS.

3.1 Introduction

OASIS, as detailed in section 1.1, are reported to be a main risk factor for anal incontinence in childbearing age women. A Cochrane systematic review of methods of repair for OASIS shows that with appropriately managed primary repair 60-80% of women following OASIS are asymptomatic of bowel symptoms at 12 months (42) . OASIS most commonly occur after a first vaginal birth and research suggests that sustaining an OASIS does not deter women from pursuing a subsequent vaginal birth (21, 64). For the majority of women who sustain OASIS the bowel symptoms they might develop in the immediate postpartum period tend to resolve a few weeks after the birth. However, little is known about the long-term impact of such injuries because of the cumulative effect of different risk factors, like subsequent birth(s). Additionally, for women who remain symptomatic it is necessary to understand the longer-term impact on bowel symptom severity and how this impacts on the woman's ongoing Quality of Life (QoL).

However, childbirth is one of several risk factors that a woman might be exposed to following sustaining an OASIS, and hence, should not be evaluated in isolation. Indeed, given that age and hormonal changes affect bowel and continence function it is imperative to understand the natural history of such complex trauma and its impact on bowel symptoms both in women who did and did not initially have any.

3.2 Aims and objectives

3.2.1 Aims

The aims of this study were to assess the natural history of OASIS and its relationship with long-term bowel function and related QoL and to identify any characteristics that may contribute to longer term bowel symptoms or impact on QoL, including subsequent birth.

3.2.2 Objectives

The objectives of this study were to:

a] identify bowel function in the immediate postnatal period and at the longer term and compare these to assess any changes

b] explore any association between bowel function in the immediate postnatal period, maternal, neonatal and birth characteristics and long-term bowel function.

c] explore any association between bowel function in the immediate postnatal period, maternal, neonatal and birth characteristics and long-term QoL.

d] explore any association between long-term bowel function and long-term QoL.

3.3 Study Design

This was a postal questionnaire-based cohort study to follow up clinic attendees.

3.4 Population

The population for this study were all women who attended either of the two specialist OASIS clinics at Birmingham Women's and Children's NHS Foundation Trust between June 2007 and January 2014. These clinics are described in section 1.4.

3.5 Outcome measures

Long-term bowel function and QoL assessed by completion of the Manchester Health questionnaire (MHQ) (54). As discussed in section 1.3, the MHQ was chosen as, from a comprehensive review of questionnaires to assess AI by Avery et al (2007) it was the most appropriate of only three questionnaires identified that demonstrated validity, reliability and responsiveness to achieve grade B recommended rating, as all others rated lower than this. (51). The MHQ was chosen as it was designed for the assessment of women only (unlike the Fecal Incontinence Scale (53) that was designed for use in both males and females), and assessment of AI only (unlike the Birmingham Bowel and Urinary Symptoms Questionnaire (55) that includes assessment of urinary incontinence that was not under investigation in this study).

The MHQ captures bowel function/symptoms experienced within the four weeks prior to completion of the questionnaire (faecal urgency, difficulty wiping, poor control of flatus, faecal incontinence) and the consequent impact on QoL reflected in nine QoL domains: General Health Perception, Incontinence Impact, Role Limitations, Physical Limitations, Social Limitations, Personal Relationships, Emotions, Sleep/Energy and Severity Measure. All of the QoL domains have more than one question to assess

them and each domain is scored, whereby a lower score equates to less impact on QoL. The scoring calculation is provided in Appendix 1.2. The MHQ questions concerning bowel function are a symptom index and do not form part of the QoL score but act as a guide to symptomatology.

3.6 Data collection

3.6.1 Demographics, OASIS characteristics and short-term bowel function data

Data on the demographic characteristics of the womens age, ethnicity, BMI, the classification of the OASIS they had sustained as per the RCOG guidelines (40) of 3A, 3B, 3C or 4 (if this was not known they were classified as 'unspecified'), and method of OASIS repair of 'overlap' or 'end-to-end' (if this was not known, repair was classified as 'unspecified'), was routinely recorded at attendances to the initial hospital clinics. The women's bowel function at the time of initial hospital consultation was also recorded from discussion rather than a self-completed questionnaire. This included information on their ability to defer a bowel motion for > 15 minutes, their control of flatus, which was categorised as 'good', 'variable' or 'poor', and the presence or absence of faecal incontinence. The mode of birth and age at which the OASIS was sustained were also recorded at the initial hospital consultation.

3.6.2 Birth history information, long-term bowel function and QoL data

To collect the long-term data a postal questionnaire was sent to all women. This included the MHQ, which, as described in section 1.3, is a validated questionnaire designed to capture bowel function and its impact on quality of life. The women

were also asked in the questionnaire to provide information concerning their labour and birth history and, for each birth, they were asked to give the date of the birth, birthweight, the type of birth, whether they had any perineal trauma/stitches, if the perineal trauma had extended into the sphincter muscles, if it was a single or multiple birth and whether there had been an epidural/spinal during the labour/birth (Appendix 3.1).

The questionnaire was posted with a Stamped Addressed Envelope (SAE) enclosed in May 2014 allowing a minimum duration of 7 months up to 7 years to have elapsed since the woman's initial hospital clinic attendance. A second mailing cycle was sent out 8 weeks later to non-responders.

3.7 Data analysis

3.7.1 Definition of characteristics

The Manchester Health Questionnaire (MHQ), as described in section 1.3, was used to assess women's bowel function and QoL (54) . This validated questionnaire captures bowel function/symptoms (faecal urgency, difficulty wiping, poor control of flatus, faecal incontinence) and consequent impact on QoL reflected in nine domains: General Health Perception, Incontinence Impact, Role Limitations, Physical Limitations, Social Limitations, Personal Relationships, Emotions, Sleep/Energy and Severity Measure. The QoL domains are calculated from a scoring system whereby a lower score equates to less impact on QoL. A score of 0 was deemed indicative of no effect on QoL as this score is calculated from the answers of 'never'. A score of ≥ 1 was deemed indicative of some negative effect on QoL as this score is calculated

from the answers of ‘rarely’, ‘sometimes’, ‘often’ and ‘always’. The questions concerning bowel function are a symptom index and do not form part of the QoL score but act as a guide to symptomatology.

For multivariate analysis faecal leakage was categorised as two independent outcome variables; ‘passive only’ faecal leakage, and ‘any’ faecal leakage which encompassed passive leakage, leakage with coughing, leaking with walking, any loose or solid leakage or leaking with sexual intercourse. For those women who attended both the 8-12 week postnatal clinic immediately following OASIS and again during their subsequent pregnancy to discuss mode of birth, symptoms recorded at their initial postnatal appointment were taken as representative of bowel function following OASIS.

In order to allow comparisons between the bowel function items routinely recorded at initial hospital consultation review and those within the MHQ, women’s response of ‘never’ for urgency to open bowels in MHQ was considered to be consistent with a good ability to defer a bowel motion at initial hospital clinic review. Likewise, women stating ‘never’ to having poor control of flatus was considered to equate to good control of flatus at initial hospital clinic review. The symptoms of faecal leakage were dichotomised into either ‘present’ or ‘not present’.

3.7.2 Statistical methods

Data were analysed using STATA® (107) and SPSS® (108). Differences in baseline characteristics between responders and non-responders, women with correct and incorrect OASIS recollection and women undergoing endoanal ultrasound scan or

not, were analysed using a two-sample t-test for continuous characteristics, a Mann-Whitney *U* test for skewed data, and a Chi-square test for categorical characteristics when the numbers in each cell were greater than or equal to five and a Fischer's exact test for categorical characteristics when the numbers in each cell were less than or equal to five. A $p<0.05$ was considered statistically significant.

A multivariate logistic regression model providing odds ratios (OR) and 95% confidence intervals (95% CI), was used to evaluate associations between possible independent characteristics (bowel symptoms at initial hospital review, maternal age at OASIS, years between OASIS and questionnaire completion, total parity, mode of birth post-OASIS, OASIS birth mode, OASIS classification, repair method and birthweight) and the primary outcomes of long-term bowel symptoms and MHQ QoL domains.

3.8 Ethical Approval

Ethical approval was gained from NRES Committee West Midlands – The Black Country (14/WM/0025). Return of the questionnaire was accepted as consent for information provided in the postal questionnaire to be used for the study. Women were also asked to indicate consent for their hospital records to be accessed for information regarding results of endoanal ultrasound scans (EAUS) which may have been undertaken. For the women who did not respond their routine data was anonymised by hospital records staff and provided as a group in order to be able to compare whether responders differed from non-responders.

3.9 Results

Of the 991 attendances at either of the specialist clinics, 41 had attended both clinics and one woman had died (cause of death unknown to the study team), leaving 945 women who were sent the questionnaire. Of these, 299 women returned questionnaires of which 294 were completed fully to allow inclusion for analysis, hence a response rate of 31%. This is shown in figure 2.1. Of the 294 women who responded, 193 (65.7%) had attended the 8-12 weeks postnatal OASIS clinic, 73 (24.8%) women had been reviewed in their subsequent pregnancy and 28 (9.5%) women had attended both a postnatal clinic following their OASIS and then the specialist antenatal clinic in a subsequent pregnancy.

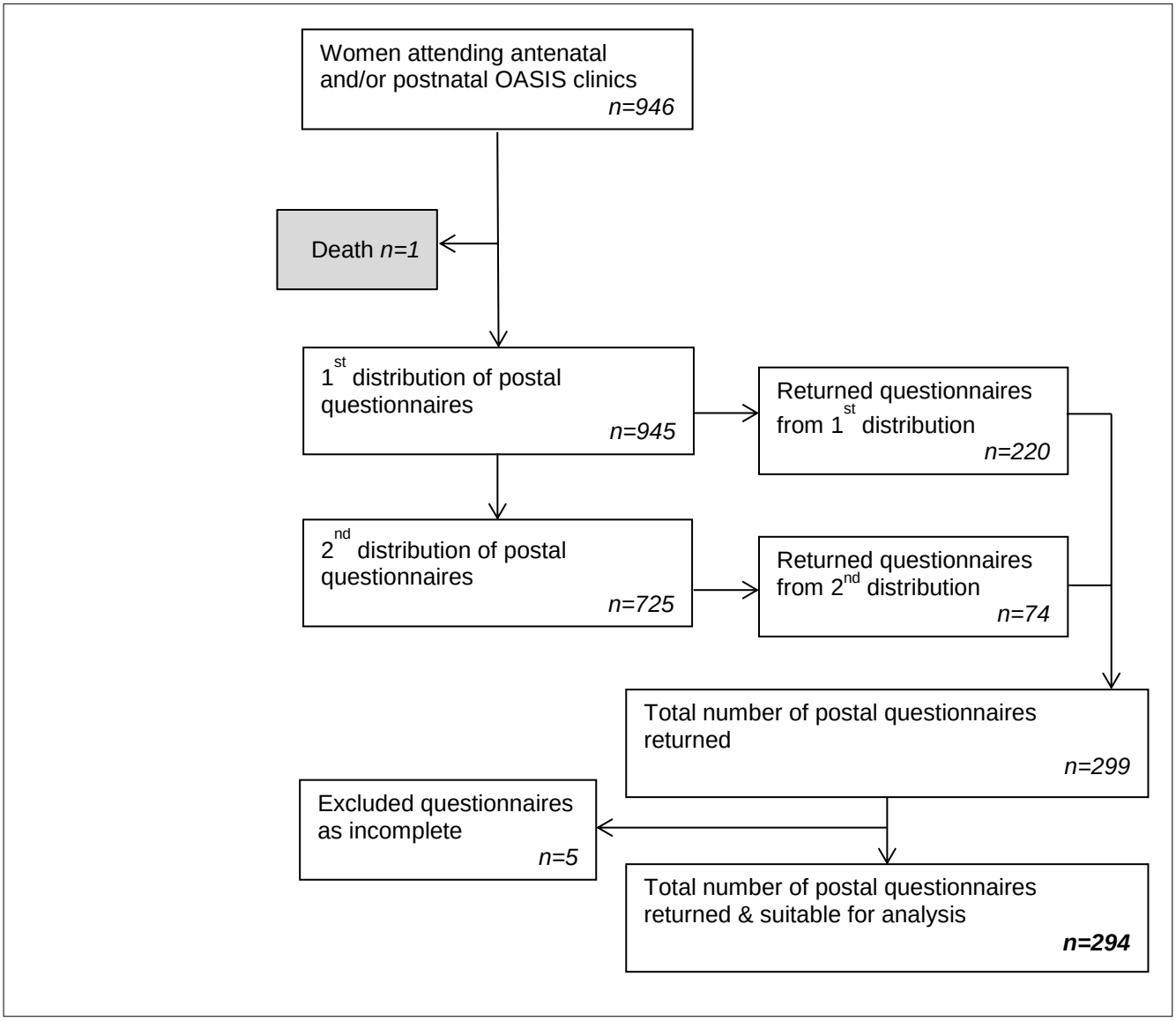


Figure 3.1 Flow chart to show postal questionnaire responses

3.9.1 Baseline characteristics of responders and comparison with non-responders

Table 3.1 shows the baseline maternal, labour, OASIS and neonatal characteristics of their last birth of the women in the study. The mean age of the women was 30 years and two-thirds of the women in the sample were white. OASIS classification showed that a 3A and 3B accounted for three quarters and type of OASIS repair was a third in each repair method group, with similar proportion in the women who did not respond. Over a third of the group had an instrumental birth and a third had an episiotomy. Table 3.1 also shows the comparison between these characteristics and those of the non-responders. This comparison was performed to determine if there were any differences in women who did not return their postal questionnaire. OASIS characteristics of trauma classification and method of repair were comparable, as were mode of birth, induction of labour, epidural, mediolateral episiotomy and maternal position at birth. Likewise, neonatal characteristics of gestational age at birth, birthweight and head circumference were comparable between the two groups. Bowel symptoms of poor control of flatus, inability to defer a bowel motion and faecal incontinence following OASIS were also comparable between the two groups. The only significant differences were in ethnicity, with more white women who returned the questionnaire compared to those who did not, and mean age of respondents was slightly older.

The mean time periods between completion of the postal questionnaire and the respondents' first birth, last birth and the birth at which they sustained the OASIS were 6.05 years (±3.53), 3.24 years (±2.13) and 5.33 years (± 2.77 years)

respectively. There were 17 women (5.7%) currently pregnant, ranging between 5 weeks $^{+3 \text{ days}}$ to 35 weeks $^{+6 \text{ days}}$ gestation at the time of questionnaire completion.

A history of all childbirth related perineal trauma for women undergoing any vaginal birth was completed by 81.3% (239/294) of the women, two of whom sustained more than one OASIS.

Table 3.1 Baseline characteristics of postal questionnaire responders and non-responders

Characteristics, n(%)	Responders N=294	Non-responders N=651	*p*-value
Maternal characteristics			
Age at OASIS (years), mean [SD]	30.2 [4.9]	28.6 [5.1]	<0.001
Ethnicity			<0.001
White	196 (66.7)	283 (43.5)	
Mixed/Multiple	5 (1.7)	17 (2.6)	
Asian/Asian British	74 (25.2)	224 (34.4)	
Black/African/Caribbean/Black British	11 (3.7)	40 (6.2)	
Other/Not Known	8 (2.7)	87 (13.4)	
BMI, mean [SD]	24.8 (3.9)	26.2 (5.0)	0.091
OASIS characteristics			
OASIS classification			0.149
3A	110 (37.4)	250 (38.4)	
3B	110 (37.4)	216 (33.2)	
3C	33 (11.2)	72 (11.1)	
4	21 (7.2)	34 (5.2)	
Unspecified	20 (6.8)	79 (12.1)	
Method of repair			
Overlap	92 (31.2)	190 (29.2)	0.615
End-to-end	105 (35.7)	254 (39.1)	
Unspecified	97 (33.1)	207 (31.7)	
Labour characteristics			
Mode of first birth at study site			0.223[≠]
SVD	183 (62.2)	384 (58.9)	
Forceps	84 (28.6)	184 (28.3)	
Kiwi/ventouse	23 (7.8)	71 (10.9)	
Caesarean section	1 (0.3)	9 (1.4)	
Unknown	3 (1.0)	3 (0.5)	
Induction of labour	60 (20)	139 (21)	0.742
Epidural	69 (23)	167 (26)	0.473
Episiotomy (all mediolateral)	98 (33)	239 (37)	0.315
Maternal position at birth			0.217
Lithotomy	110 (37.4)	287 (44.1)	
Supported sitting	80 (27.2)	188 (28.9)	
All fours	9 (3.1)	13 (1.9)	
Standing	7 (2.4)	14 (2.2)	
Lateral	9 (3.1)	19 (2.9)	
Kneeling	23 (7.8)	33 (5.1)	
McRoberts	13 (4.4)	34 (5.2)	
Squatting	1 (0.3)	2 (0.3)	
Not known	42 (14.3)	61 (9.4)	
Neonatal characteristics			
Gestational age, (weeks), median [IQR][¥]	40 [39, 41]	40 [39, 41]	0.746
Birth weight, (kg), mean (SD)	3.533 (0.533)	3.468 (0.498)	0.069
Head circumference (cms), mean (SD)	34.5 (2.1)	34.6 (2.4)	0.837

Bowel function following OASIS			
Control of flatus			0.981≠
Good	235 (79.9)	494 (75.8)	
Variable	45 (15.3)	92 (14.1)	
Poor	14 (4.8)	28 (4.3)	
Not known	0	6 (0.9)	
Ability to defer bowel motion			0.179≠
Good (>15 mins)	224 (76.2)	503 (77.3)	
Variable	41 (13.9)	70 (10.8)	
Poor	29 (9.9)	45 (6.9)	
Not known	0	33 (5.0)	
Faecal Incontinence	17 (6.7)	29 (4.5)	0.486≠

IQR: interquartile range; SD: standard deviation.
The *t* test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data)¥, and χ^2 test for categorical characteristics with missing excluded as appropriate due to small numbers≠

3.9.2 Birth history

Table 3.2 shows the mode birth history for the respondents. Within the sample, 90 of the women (30.6%) had only undergone the birth at which the OASIS was sustained. There were 260 women (88.4%) for whom OASIS had occurred at their first vaginal birth, nine of whom had given birth by caesarean section prior to the vaginal birth in which they sustained an OASIS. After their OASIS birth, there were 120 women (40.8%) who had no further births. Of the remaining 174 women who did have another birth after the OASIS, 55.1% (108/196) had a subsequent vaginal birth. From the respondents 204 (69.4%) of the women had a parity of ≥ 2, with 66 (32.4%) of these women having a subsequent birth by caesarean section only.

With regard to the total number of births women had had, out of the 294 women who returned the questionnaire 30.6% (90/294) had only had one birth, 52.7% (155/294) had given birth twice and 16.7% (49/294) had three or more births.

Table 3.2 Birth mode history for questionnaire responders

All respondents, n (%)	Pre OASIS birth mode: None		Vaginal birth only		Caesarean section only		Total	
Post- OASIS birth mode								
None	90	(75.0)	23	(19.7)	7	(5.8)	120	(100)
Vaginal birth(s) only	97	(92.4)	7	(6.7)	1	(0.9)	105	(100)
Caesarean section(s) only	61	(92.4)	4	(6.1)	1	(1.5)	66	(100)
Both vaginal and caesarean	3	(100)	0		0		3	(100)
Total	251		34		9		294	

3.9.3 Recollection of sustaining OASIS

For each labour and birth, women were asked in the postal questionnaire to indicate if the perineal trauma sustained during each birth had extended into the anal sphincter muscles , with the options of 'Yes', 'No' or 'Don't know'. 81.3% (239/294) of the women had a correct recollection, 5.9 % (17/294) of the women had incorrect recollection and 12.9% (38/294) women did not know. These three groups were then compared to determine if there was any difference in the women that may account for the accuracy of their recollection (table 3.3), but no differences were found. Baseline maternal characteristics of age at OASIS, ethnicity, BMI and parity for all three groups were comparable, as were OASIS characteristics of trauma classification and method of repair. The labour characteristics during which OASIS was sustained for mode of OASIS birth, whether the OASIS birth was induced, involved epidural anaesthesia, episiotomy and maternal position at the time of birth, were also comparable between the three groups. Likewise, neonatal characteristics of the OASIS birth of gestational age, birth weight and head circumference were all comparable between the two groups. With regards to bowel function following the OASIS, bowel symptoms of poor control of flatus, inability to defer a bowel motion and faecal incontinence following OASIS were also comparable between the groups.

Table 3.3 Baseline characteristics of questionnaire responders in relation to recollection of sustaining OASIS

Characteristics, n (%)	Correct recollection n=239	Incorrect recollection n=17	Did not know n=38	*p*-value[≠]
Maternal characteristics				
Age at OASIS (years), mean [SD]	30.4 [4.9]	30.0 [5.7]	29.2 [4.9]	0.488
Time between OASIS and questionnaire completion (years), mean [SD]	6.1 [2.9]	5.2 [2.1]	5.5 [2.0]	0.413
Ethnicity				0.194
White	165 (69.0)	9 (52.9)	22 (57.9)	
Mixed/Multiple	4 (1.7)	0	1 (2.6)	
Asian/Asian British	57 (23.9)	6 (35.3)	11 (29.0)	
Black/African/Caribbean/Black British	8 (3.4)	0	3 (7.9)	
Other/Not Known	5 (2.1)	2 (11.8)	1 (2.6)	
BMI, mean [SD]	24.5	26.0	26.3	0.544
Parity				0.088
1	71 (29.7)	5 (29.4)	14 (36.8)	
2	132 (55.2)	10 (58.8)	13 (34.2)	
≥ 3	36 (15.1)	2 (11.8)	11 (29.0)	
OASIS characteristics				
OASIS classification				0.064
3A	83 (34.7)	6 (35.3)	21 (55.3)	
3B	92 (38.5)	5 (29.4)	13 (34.2)	
3C	30 (12.6)	2 (11.8)	1 (2.6)	
4	20 (8.4)	1 (5.9)	0	
Unspecified	14 (5.9)	3 (17.6)	3 (7.9)	
Method of repair				0.521
Overlap	79 (33.1)	6 (35.3)	8 (21.0)	
End-to-end	81 (33.9)	5 (29.4)	18 (47.4)	
Unspecified	79 (33.1)	6 (35.3)	12 (31.6)	
Labour characteristics				
Mode of OASIS birth				0.158
SVD	151 (63.2)	12 (70.6)	20 (52.6)	
Forceps	73 (30.5)	4 (23.5)	11 (29.0)	
Kiwi/ventouse	15 (6.3)	1 (5.9)	7 (18.4)	
Induction of labour	49 (20.5)	3 (17.7)	8 (21.1)	1.000
Epidural	52 (21.8)	4 (23.5)	13 (34.2)	0.251
Episiotomy (all mediolateral)	79 (33.1)	6 (35.3)	13 (34.2)	1.000
Maternal position at birth				0.300
Lithotomy	86 (36.0)	8 (47.1)	16 (42.1)	
Supported sitting	65 (27.2)	5 (29.4)	10 (26.3)	
All fours	7 (2.9)	2 (11.8)	0	
Standing	7 (2.9)	0	0	
Lateral	5 (2.1)	0	4 (10.5)	
Kneeling	20 (8.4)	1 (5.9)	2 (5.3)	
McRoberts	9 (3.8)	0	4 (10.5)	
Squatting	1 (0.4)	0	0	

Not known	39 (16.3)	1 (5.9)	2 (5.3)	
Neonatal characteristics				
Gestational age, (weeks), median [IQR]¥	40	40	40	
Birth weight, (kg), mean [SD]	3537 [0.543]	3494 [0.477]	3529 [0.508]	0.948
Head circumference (cms), mean [SD]	35 [2]	35 [2]	34 [1]	0.986
Bowel function following OASIS				
Control of flatus				0.179
Good	184 (77.0)	16 (94.1)	35 (92.1)	
Variable	41 (17.2)	1 (5.9)	3 (7.9)	
Poor	14 (5.6)	0	0	
Ability to defer bowel motion				0.227
Good (>15 mins)	175 (73.2)	16 (94.1)	33 (86.8)	
Variable	37 (15.3)	1 (5.9)	3 (7.9)	
Poor	27 (11.3)	0	2 (5.3)	
Not known				
Faecal Incontinence	17 (7.1)	0	0	0.181

IQR: interquartile range; SD: standard deviation.
The ANOVA test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data)¥, and Fischer exact test for categorical characteristics with missing excluded as appropriate due to small numbers≠

3.9.4 Bowel function

Table 3.4 shows the incidence of bowel symptoms at the time of questionnaire completion. There were 76.5% (225/294) of the women who reported having experienced any episode of faecal urgency and 66.3% (195/294) of the women had experienced poor control of flatus at any time. Difficulty in wiping clean after a bowel motion was experienced by 42.9% (126/294) women. With regard to faecal leakage, 35.7% (105/294) of the women reported having had any type of leakage on any occasion. Of the various occasions when leakage occurred, the most common was faecal leaking with coughing which had been experienced by 22.8% (67 /294) of the women. The least common occasion of faecal leakage was during sexual intercourse that was experienced by 5.1% (15/294) of the women. All faecal leakage was of loose stools as no woman had reported ever experiencing solid faecal incontinence. Further analysis of bowel symptoms of individual women showed that 9.2% (27/294) women had no symptoms, 18.4% (54/294) had one symptom, 24.3% (73/294) reported two bowel symptoms and the remainder had ≥ three symptoms.

Table 3.4 Bowel symptoms at questionnaire completion

				Faecal Leakage						
Respondents N=294, n (%)	Faecal urgency	Difficulty wiping clean	Poor control of flatus	Leak passive-only	Leak with coughing	Leak with walking	Leak during SI	Loose leakage	Solid leakage	Any faecal leakage
Never	69 (23.5)	168 (57.1)	99 (33.7)	269 (91.5)	227 (77.2)	262 (89.1)	270 (91.8)	216 (73.5)	294 (100)	189 (64.3)
Occasionally	126 (42.9)	68 (23.1)	87 (29.6)	16 (5.5)	37 (12.6)	20 (6.8)	12 (4.1)	39 (13.3)	0	105 (35.7)
Sometimes	75 (25.5)	35 (11.9)	64 (21.8)	9 (3.1)	24 (8.2)	11 (3.7)	2 (0.7)	23 (7.8)	0	
Most of the time	21 (7.1)	14 (4.8)	32 (10.9)	0	2 (0.7)	1 (0.3)	1 (0.3)	12 (4.1)	0	
All of the time	3 (1.0)	9 (3.1)	12 (4.1)	0	3 (1.0)	0	0	4 (1.4)	0	
Not stated	0	0	0	0	1 (0.3)	0	9 (3.1)	0	0	

Univariate analyses were undertaken to show the relationship between bowel symptoms at postnatal questionnaire completion and post OASIS births. These are shown in Tables 3.5 and 3.6. Of the 225 women who had faecal urgency at postnatal questionnaire completion, 44% (99/225) of them had not had a subsequent birth. Of the 195 women who had poor control of flatus at postnatal questionnaire completion, 44.1% (86/195) of them had not had a subsequent birth (Table 3.5).

With regard to faecal leakage, of the 105 women who had faecal leakage of any type at questionnaire completion, 50.5% (53/105) of them had not had a post OASIS birth. Passive only faecal leakage occurred in 25 women at the time of postnatal questionnaire completion, of which 40% (10/25) had not had a subsequent birth. For each of the four bowel symptoms, a greater proportion of women who had not had a birth following that in which the OASIS was sustained had bowel symptoms when compared to women who had had any subsequent birth(s) either vaginally or by caesarean section (Table 3.6).

Table 3.5 Relationship between bowel symptoms of poor control of flatus and faecal urgency at postnatal questionnaire completion and post OASIS births

	Faecal Urgency *At postal questionnaire completion*			**Poor control of flatus** *At postal questionnaire completion*		
	Absent	Present	Total	Absent	Present	Total
Post OASIS births, n (%)						
None	21 (17.5)	99 (82.5)	120 (100)	34 (28.3)	86 (71.7)	120 (100)
Vaginal	31 (28.7)	77 (71.3)	108 (100)	40 (37.0)	68 (63.0)	108 (100)
Caesarean section	17 (25.8)	49 (74.2)	66 (100)	25 (39.7)	41 (62.1)	66 (100)
Total	69	225	294	99	195	294

Table 3.6 Relationship between bowel symptoms of faecal leakage at postnatal questionnaire completion and post OASIS births

	Faecal leakage - any[≠] *At postal questionnaire completion*			**Faecal leakage – passive only** *At postal questionnaire completion*		
	Absent	Present	Total	Absent	Present	Total
Post OASIS births, n (%)						
None	67 (55.8)	53 (44.2)	120 (100)	108 (90.0)	12 (10.0)	120 (100)
Vaginal	73 (67.6)	35 (32.4)	108 (100)	9 (8.3)	9 (8.3)	108 (100)
Caesarean section	49 (74.2)	17 (25.8)	66 (100)	4 (6.1)	4 (6.1)	66 (100)
Total	189	105	294	269	25	294

[≠] Any episode of passive leakage, leakage with coughing, leaking with walking, any loose or solid leakage or leaking with sexual intercourse.

Comparisons of women's bowel symptoms for women between those reported at initial hospital clinic review and at postal questionnaire completion were undertaken to see if there was any change (worsening or improvement) in bowel symptoms over the longer term. These are shown in Tables 3.7 and 3.8. Among the 59 women who had faecal urgency either sometimes or frequently at hospital review following the OASIS there was an improvement in this in the longer term for 16.9% (10/59) of women. Among the 70 women who experienced poor control of flatus either sometimes or frequently at hospital review following the OASIS there was an improvement in this for 37.1% (26/70) of women. However, of the 235 women who had never had faecal urgency at hospital review post OASIS, 60.0% (141/235) did have faecal urgency at long-term follow-up. Of the 224 women who had never had poor control of flatus post OASIS, 71.9% (161/235) had poor control of flatus at long-term follow-up (Table 3.7).

At questionnaire completion any faecal leakage and passive only faecal leakage had resolved in 29.4% (5/17) and 82.4% (14/17) of women respectively who had experienced these symptoms following the OASIS. However, 7.9% (22/277) of women reported having any faecal leakage and 33.6% (93/277) of women reported having passive only faecal leakage at long-term follow up who had not had these symptoms post OASIS (Table 3.8).

Table 3.7 Comparison of bowel symptoms of flatus control and faecal urgency at initial hospital clinic review and at postal questionnaire completion

	Faecal Urgency *At postal questionnaire completion*				**Poor control of flatus** *At postal questionnaire completion*			
	Never	Occasionally/ Sometimes	Most of the time/ All of the time	Total	Never	Occasionally/ Sometimes	Most of the time/ All of the time	Total
At initial hospital clinic review, n (%)								
Never	94 (40.0)	114 (48.5)	27 (11.5)	235 (100)	63 (28.1)	149 (66.4)	12 (5.6)	224 (100)
Sometimes	4 (8.9)	32 (71.1)	9 (20.0)	45 (100)	4 (9.8)	32 (78.0)	5 (12.2)	41 (100)
Frequently	1 (7.1)	5 (35.7)	8 (57.1)	14 (100)	2 (6.9)	20 (68.9)	7 (24.2)	29 (100)
Total	99	151	44	294	69	201	24	294

Table 3.8 Comparison of bowel symptoms of faecal leakage at initial hospital clinic review and at postal questionnaire completion

	Faecal Leakage – Any[≠] *At postal questionnaire completion*			**Faecal Leakage - Passive only** *At postal questionnaire completion*		
	Not Present	Present	Total	Not Present	Present	Total
At initial hospital clinic review, n (%)						
Not Present	184 (66.4)	93 (33.6)	277 (100)	255 (92.1)	22 (7.9)	277 (100)
Present	5 (29.4)	12 (70.6)	17 (100)	14 (82.4)	3 (17.6)	17 (100)
Total	189	105	294	269	25	294

[≠] Any episode of passive leakage, leakage with coughing, leaking with walking, any loose or solid leakage or leaking with sexual intercourse.

3.9.5 Multivariate analysis of the association between short-term bowel function, maternal, intrapartum, OASIS and neonatal characteristics and long-term bowel function

To examine the relationship between short-term bowel function following OASIS and longer term bowel function (poor control of flatus, faecal urgency, faecal leakage – any and faecal leakage – passive only), a multivariate logistic regression model was used with bowel function at postnatal questionnaire completion (long-term) as the outcome and bowel function at initial hospital clinic review (short-term) as covariates with adjustment for contributory maternal, intrapartum, OASIS and neonatal characteristics. This is shown in table 3.9.

Variable control of flatus following OASIS (short-term) was significantly associated with long-term poor control of flatus (OR 7.16, 95% CI 2.30-22.22). Faecal urgency experienced 'sometimes' (short-term) was significantly associated with long-term faecal urgency (OR 3.86, 95% CI 1.20-12.40) and long-term passive-only faecal leakage (OR 4.95; 95% CI 1.49-16.41). Short-term faecal urgency reported 'frequently' did not appear to be significantly (p<0.05) associated with long-term faecal urgency or passive-only faecal leakage but this is perhaps due to fewer participants reporting more severe symptoms.

There were no significant short-term symptoms associated with any faecal leakage in the longer term. Multivariate analysis of maternal, intrapartum, OASIS and neonatal characteristics on bowel function at questionnaire completion demonstrated an improvement in ability to control flatus in the longer term for women having

subsequent births by caesarean only (OR 0.22; 95% CI 0.06-0.77) compared to women with no subsequent birth(s). A 3B OASIS was significantly associated ongoing faecal urgency (OR 2.16; 95% CI 1.05-4.42). There were no significant characteristics associated with long-term faecal leakage (any or passive-only).

Due to the low number of events, the results of this multivariate analysis need to be interpreted with caution as some of the confidence intervals are large and therefore precision of the estimates is low.

Table 3.9 Multivariate analysis of the association between short-term bowel function, maternal intrapartum, OASIS and neonatal characteristics and long-term bowel function

Characteristic (n/294)		Bowel symptoms at questionnaire completion: Mean 5.82 years (±3.37)											
		Poor control of flatus			Faecal urgency			Faecal Leakage – Any[≠]			Faecal Leakage – Passive only		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at initial hospital clinic review													
Faecal urgency													
Never	(224)											Reference	
Sometimes	(41)	2.22	(0.83-5.91)	0.112	3.86	(1.20-12.40)	*0.023*	1.66	(0.76-3.62)	0.203	4.95	(1.49-16.41)	*0.009*
Frequently	(29)	2.80	(0.83-9.47)	0.097	4.71	(0.97-22.89)	0.055	1.46	(0.57-3.74)	0.434	3.68	(0.84-16.13)	0.083
Control of flatus													
Good	(235)											Reference	
Variable	(45)	7.16	(2.30-22.22)	*0.001*	1.60	(0.58-4.41)	0.361	0.66	(0.30-1.42)	0.282	0.54	(0.13-2.23)	0.395
Poor	(14)	4.90	(0.56-42.64)	0.150	0.64	(0.11-3.64)	0.616	2.15	(0.61-7.60)	0.236	1.07	(0.17-6.91)	0.942
Maternal characteristics													
Age at OASIS		1.04	(0.98-1.10)	0.211	1.00	(0.94-1.07)	0.950	1.01	(0.96-1.07)	0.688	1.01	(0.92-1.11)	0.793
Years between OASIS and questionnaire completion		1.05	(0.91-1.20)	0.501	0.97	(0.83-1.14)	0.713	1.05	(0.92-1.19)	0.510	1.15	(0.92-1.44)	0.220
Parity (all birth modes)													
1	(90)											Reference	
2	(155)	1.65	(0.50-5.50)	0.412	0.72	(0.21-2.47)	0.602	1.01	(0.40-2.58)	0.978	1.13	(0.14-1.17)	0.069
≥ 3	(49)	2.82	(0.67-11.97)	0.159	0.99	(0.23-4.39)	0.994	1.26	(0.39-4.12)	0.700	0.19	(0.16-2.33)	0.194
Post-OASIS births													
None	(120)											Reference	

Vaginal [¥]	(108)	0.43	(0.13-1.42)	0.165	0.50	(0.15-1.66)	0.257	0.66	(0.25-1.77)	0.412	3.52	(0.33-37.81)	0.299
Caesarean section only	(66)	0.22	(0.06-0.77)	*0.018*	0.44	(0.13-1.53)	0.199	0.37	(0.13-1.08)	0.069	1.81	(0.15-21.68)	0.642
Intrapartum characteristics													
OASIS birth mode													
SVD	(183)											Reference	
Kiwi	(23)	0.62	(0.22-1.74)	0.366	1.53	(0.46-5.15)	0.488	2.52	(0.98-6.46)	0.055	1.02	(0.20-5.32)	0.982
Low/unspecified forceps	(57)	1.88	(0.87-4.07)	0.111	2.22	(0.90-5.46)	0.083	1.29	(0.65-2.57)	0.465	0.55	(0.15-1.97)	0.357
Rotational forceps	(30)	0.55	(0.21-1.49)	0.243	0.40	(0.13-1.17)	0.095	1.63	(0.64-4.10)	0.304	1.04	(0.22-4.87)	0.962
OASIS characteristics													
OASIS classification													
3A	(110)											Reference	
3B	(110)	0.282	(0.75-2.71)	0.282	2.16	(1.05-4.42)	*0.036*	0.68	(0.36-1.27)	0.222	0.92	(0.30-2.85)	0.880
3C/4	(54)	0.525	(0.58-2.90)	0.525	1.92	(0.79-4.67)	0.151	1.04	(0.48-2.23)	0.923	1.27	(0..33-4.95)	0.732
Unspecified	(20)	0.114	(0.77-11.38)	0.114	1.03	(0.28-3.80)	0.970	1.81	(0.57-5.74)	0.316	2.38	(0.38-14.89)	0.353
OASIS repair method													
End-to-end	(105)											Reference	
Overlap	(92)	0.555	(0.61-2.50)	0.555	1.21	(0.57-2.60)	0.618	0.89	(0.46-1.72)	0.726	0.77	(0.24-2.53)	0.671
Unspecified	(97)	0.485	(0.60-2.92)	0.485	2.18	(0.91-5.24)	0.082	0.72	(0.32-1.60)	0.414	0.74	(0.17-3.16)	0.684
Neonatal characteristics													
Birthweight		0.915	(1.00-1.00)	0.915	1.00	(1.00-1.00)	0.118	1.00	(1.00-1.00)	0.580	1.00	(1.00-1.00)	0.370

[¥] includes four women with a combination of vaginal and caesarean section mode of post OASIS births

3.9.6 Bowel function and Endoanal Ultrasound Scan findings

There were 117 (39.8%) of the 294 respondents who had undergone an endoanal anal ultrasound scan (EAUS) at their three months postnatal clinic visit to confirm anatomical integrity of the anal sphincter muscles. Additional analysis was undertaken on the group for whom scans were performed to examine the relationship between sphincter integrity and long-term bowel function.

Firstly the group of women who had undergone EAUS were compared with those who had not to see if there were any differences within their baseline characteristics (Table 3.10). Baseline maternal characteristics of age at OASIS, ethnicity, BMI and parity were comparable. The OASIS trauma classification was also comparable between the two groups. However, there was a significant difference in the method of OASIS repair between the groups. The labour characteristics during which OASIS was sustained, for mode of birth, whether the birth was induced, involved epidural anaesthesia, episiotomy and maternal position at the time of birth, were also comparable between the two groups. Likewise, neonatal characteristics were comparable between the two groups. With regards to bowel function following the OASIS, bowel symptoms of inability to defer a bowel motion and faecal incontinence following OASIS were comparable between the two groups. However, there was a significant difference in the symptom of poor control of flatus between the two groups. Although there were more women who had good or variable control of flatus in the group who did not have EAUS, this group had a much higher number of women with poor control of flatus.

Table 3.10 Baseline characteristics of women having EAUS and no EAUS.

Characteristics, n (%)	EAUS n=117	No EAUS n=177	*p*-value
Maternal characteristics			
Age at OASIS (years), mean [SD]	30.7 [4.6]	30.0 [5.1]	0.884
Ethnicity			0.364
White	83 (70.9)	113 (63.8)	
Mixed/Multiple	1 (0.9)	4 (2.3)	
Asian/Asian British	27 (23.1)	47 (26.6)	
Black/African/Caribbean/Black British	5 (4.3)	6 (3.4)	
Other/Not Known	1 (0.9)	7 (3.9)	
BMI, mean [SD]	24.7 [3.6]	25.0 [4.5]	0.818
OASIS characteristics			
OASIS classification			0.175
3A	38 (32.5)	72 (40.7)	
3B	38 (32.5)	72 (40.7)	
3C	21 (17.9)	12 (6.8)	
4	11 (9.4)	10 (5.6)	
Unspecified	9 (7.7)	11 (6.2)	
Method of repair			*0.024*
Overlap	26 (22.2)	66 (37.3)	
End-to-end	48 (41.0)	57 (32.2)	
Unspecified	43 (36.8)	54 (30.5)	
Labour characteristics			
Mode of OASIS birth			0.912
SVD	70 (59.8)	113 (63.8)	
Forceps	37 (31.7)	51 (27.2)	
Kiwi/ventouse	10 (8.5)	13 (7.3)	
Induction of labour	26	34	0.530
Epidural	27	42	0.897
Episiotomy (all mediolateral)	43	55	0.312
Maternal position at birth			0.196
Lithotomy	44 (37.6)	66 (37.6)	
Supported sitting	28 (23.9)	52 (29.4)	
All fours	1 (0.9)	8 (4.5)	
Standing	1 (0.9)	6 (3.4)	
Lateral	5 (4.3)	4 (2.3)	
Kneeling	9 (7.7)	14 (7.9)	
McRoberts	7 (6.0)	6 (3.4)	
Squatting	1 (0.9)	0	
Not known	21 (17.9)	21 (11.9)	
Neonatal characteristics			
Gestational age, (weeks), median [IQR]¥	40 [39,42]	40 [39,42]	0.345
Birth weight, (kg), mean (SD)	3.532 [0.508]	3.565 [0.586]	0.809
Head circumference (cms), mean (SD)	34.4 [1.6]	34.6 [2.3]	0.393
Bowel function following OASIS			

Control of flatus			*0.030*
Good	89 (76.1)	146 (82.5)	
Variable	25 (21.4)	20 (11.3)	
Poor	3 (2.6)	11 (6.2)	
Not known	0	0	
Ability to defer bowel motion			0.585
Good (>15 mins)	88 (75.2)	136 (76.8)	
Variable	15 (12.8)	26 (14.7)	
Poor	14 (12.0)	15 (8.5)	
Not known			
Faecal Incontinence	5 (4.3)	12 (6.8)	0.368

IQR: interquartile range; SD: standard deviation.
The *t* test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data) [¥], and Fischer exact test for categorical characteristics with missing excluded as appropriate due to small numbers

Of the group of 117 women who had undergone EAUS, 17 (14.5%) were diagnosed with an anal sphincter abnormality, five of whom had extensive scarring or sphincter defect in the EAS only and 12 women who had a sphincter abnormality in both the EAS and IAS. There were no women who had a defect in the IAS only. Table 3.11 shows bowel function at questionnaire completion for the 117 women who had undergone EAUS. Faecal urgency was the only bowel symptom that was significantly associated with the presence of extensive scarring or anal sphincter defect (p=0.009) (Table 3.11). Further comparison of the women with known extensive scarring or anal sphincter defect by the extent of damage showed that women with abnormalities in the EAS only were significantly more likely to have poor control of flatus compared to women with a defect to the EAS and IAS (*p*=0.036) (Table 3.12).

Table 3.11 Bowel function at questionnaire completion for respondents who had EAUS

	Poor control of flatus		**Faecal urgency**		**Faecal leakage - Any[≠]**		**Faecal leakage – Passive only**	
Respondents having EAUS, N=117, n (%)	Yes	No	Yes	No	Yes	No	Yes	No
Extensive scarring or sphincter defect present , n=17	9 (23.1)	8 (10.3)	11 (25.5)	6 (8.1)	6 (15.4)	11 (14.1)	2 (22.2)	15 (13.9)
No sphincter abnormality, n=100	30 (72.9)	70 (89.7)	32 (74.5)	68 (91.9)	33 (84.6)	67 (85.9)	7 (77.8)	93 (86.1)
Total	39	78	43	74	39	78	9 (7.7)	108
	p=0.063		*p=0.009*		*p*=0.853		*p*=0.496	

[≠] Any episode of passive leakage, leakage with coughing, leaking with walking, any loose or solid leakage or leaking with sexual intercourse.

Table 3.12 Bowel function at questionnaire completion for women with extensive scarring or sphincter defect on EAUS

	Poor control of flatus		**Faecal urgency**		**Faecal leakage - Any[≠]**		**Faecal leakage – Passive only**	
Extensive scarring or sphincter defect present [¥], N=17, n (%)	Yes	No	Yes	No	Yes	No	Yes	No
IAS + EAS, n=5	1 (10.0)	4 (57.1)	1 (16.7)	4 (36.4)	1 (16.7)	4 (36.4)	1 (16.7)	4 (36.4)
EAS only, n=12	9 (90.0)	3 (42.9)	5 (83.3)	7 (63.6)	5 (83.3)	7 (63.6)	5 (83.3)	7 (63.6)
Total	10	7	6	11	6	11	6	11
	p=0.036		*p*=0.394		*p*=0.394		*p*=0.394	

[¥] No woman had IAS defect only.
[≠] Any episode of passive leakage, leakage with coughing, leaking with walking, any loose or solid leakage or leaking with sexual intercourse.

3.9.7 Quality of Life scores

One of the primary aims of the study was to assess the longer term QoL for women who had sustained an OASIS and this is shown in table 3.13. As detailed in section 1.3 the MHQ captures bowel function/symptoms (faecal urgency, difficulty wiping, poor control of flatus, faecal incontinence) and the consequent impact of these on QoL as reflected in nine QoL domains: General Health Perception, Incontinence Impact, Role Limitations, Physical Limitations, Social Limitations, Personal Relationships, Emotions, Sleep/Energy and Severity Measure. All of the domains have more than one question to assess them and scores are calculated from a scoring system whereby a lower score equates to less impact on QoL (see section 1.3 and Appendix 1.2 for details of scoring). The domains least affected were 'Social Limitations' and 'Sleep/Energy'. Across the nine QoL domains 24.8-79.9% of women found their bowel function at questionnaire completion had no impact (score = 0) on their QoL; between 13.9-65.0% found bowel function 'rarely' (score1-25) had a negative QoL impact; between 4.1-11.2% found bowel function 'sometimes' (score 26-50) had a negative QoL impact, between 0.7-5.4% of women found their bowel function 'often' (score 51-75) had negative QoL impact and between 0-2.0% found their bowel function 'always' (score 76-100) had a negative impact on their QoL.

Table 3.13 MHQ QoL domain scores for questionnaire respondents

	MHQ QoL domain																	
Total score, n (%)	General Health Perception		Incontinence Impact		Role Limitations		Physical Limitations		Social Limitations		Personal Relationships		Emotions		Sleep / Energy		Severity Measures	
0	108	(36.7)	119	(40.5)	73	(24.8)	213	(72.4)	235	(79.9)	225	(76.5)	165	(56.1)	226	(76.9)	147	(50.0)
1-25	155	(52.7)	134	(45.6)	191	(65.0)	51	(17.3)	41	(13.9)	45	(15.6)	79	(26.9)	49	(16.7)	93	(31.6)
26-50	25	(8.5)	19	(6.5)	28	(9.5)	21	(7.1)	12	(4.1)	13	(4.5)	29	(9.9)	15	(5.1)	33	(11.2)
51-75	4	(1.4)	16	(5.4)	2	(0.7)	7	(2.4)	4	(1.4)	4	(1.4)	17	(5.8)	2	(0.7)	15	(5.1)
76-100	2	(0.7)	6	(2.0)	0		2	(0.7)	2	(0.7)	2	(0.7)	4	(1.4)	2	(0.7)	6	(2.0)
	294		294		294		294		294		289 [≠]		294		294		294	

[#] Not applicable to five women who were not in a personal relationship at the time of questionnaire completion

Further analysis of the relationship between the number of bowel symptoms reported and the number of QoL domains showing a negative impact for the women is provided in table 3.14. This showed that only 16 women found their bowel symptoms had no negative effect on any of the nine QoL domains despite 81.2% (13/16) of these women experiencing ≥ 1 bowel symptom. 24 women reported a negative impact on one or more of the nine QoL despite not having any bowel symptoms and 22 women found their bowel symptoms had a negative impact on all of the nine QoL domains.

Table 3.14 The relationship between the total number bowel symptoms and the QoL domains scores

Number of bowel symptoms	QoL score = 0, n (%) All nine QoL domains		QoL score ≥ 0, n (%) One QoL domain		Two QoL domains		Three QoL domains		Four QoL domains		Five QoL domains		Six QoL domains		Seven QoL domains		Eight QoL domains		Nine QoL domains	
0	3	(18.8)	13	(26.0)	8	(14.8)	2	(5.1)	0		0		0		0		0		1	(4.5)
1	4	(25.0)	14	(28.0)	22	(40.7)	8	(20.5)	3	(10.7)	4	(18.2)	2	(8.7)	0		0		0	
2	4	(25.0)	15	(30.0)	15	(27.8)	8	(20.5)	10	(35.7)	5	(22.7)	9	(39.1)	6	(26.1)	2	(11.8)	2	(9.1)
3	3	(18.8)	8	(16.0)	6	(11.1)	15	(38.5)	7	(25.0)	7	(31.8)	5	(21.7)	7	(30.4)	4	(23.5)	3	(13.6)
4	1	(6.3)	0		1	(1.9)	5	(12.8)	6	(21.4)	3	(13.6)	2	(8.7)	2	(8.7)	3	(17.6)	3	(13.6)
5	1	(6.3)	0		2	(3.7)	1	(2.6)	2	(7.1)	3	(13.6)	0		3	(13.0)	3	(17.6)	6	(27.3)
6	0		0		0		0		0		0		4	(17.4)	1	(4.3)	3	(17.6)	2	(9.1)
7	0		0		0		0		0		0		1	(4.3)	4	(17.4)	0		2	(9.1)
8	0		0		0		0		0		0		0		0		2	(11.8)	3	(13.6)
9	0		0		0		0		0		0		0		0		0		0	
	16	(5.4)	50	(17.0)	54	(18.4)	39	(13.3)	28	(9.5)	22	(7.5)	23	(7.8)	23	(7.8)	17	(5.8)	22	(7.5)

3.9.8 Multivariate analysis of the association between short-term bowel function following OASIS, maternal, intrapartum, OASIS and neonatal characteristics and long-term QoL

An aim of the study was to identify any significant independent characteristics that may contribute to longer term QoL. Table 3.15 shows the multivariate analysis investigating the association between short-term bowel function (at initial hospital clinic review following the OASIS) and maternal, intrapartum, OASIS and neonatal characteristics with the outcome of a negative impact (MHQ domain score of ≥ one) for each of the nine MHQ QoL domains at long-term questionnaire completion. The odds of poor QoL for the domains of 'Incontinence Impact' (OR 2.45; 95% CI 1.08-5.58), 'Physical Limitations' (OR 2.61; 95% CI 1.14-5.97), and 'Social Limitations' (OR 3.68; 95% CI 1.53-8.84) were significantly higher for women who had experienced faecal urgency 'sometimes' following the OASIS compared with women who had never experienced faecal urgency. The odds of poor QoL for the domains 'Personal Relationships' (OR 4.58; 95% CI 1.22-17.23) and 'Emotions' (OR6.56; 95% CI 1.31-32.88) were significantly higher for women who had 'poor' of control of flatus in the short-term period following OASIS when compared to women who had good flatal control. There were too few events of faecal leakage reported at the initial hospital clinic review following the OASIS to include this as an independent characteristic.

With regard to parity, the odds of poor QoL for the 'Sleep/Energy' domain were significantly higher in women with a parity of two (OR 3.34; 95% CI 1.20-9.33), and women having a total parity of three or more (OR 4.63; 95% CI 1.28-16.76)

compared with women with a total parity of one. For the mode of birth(s) following OASIS, the odds of poor 'General Health Perception' QoL (OR 0.18; 95% CI 0.06-0.60) and 'Sleep/Energy' (OR 0.24; 95% CI 0.07-0.68) were both significantly lower for women that had a subsequent birth(s) by caesarean section compared with women who had no subsequent births. Regarding the extent of the OASIS, the odds of poor QoL for the domain of 'Role Limitations' were higher in women with a 3C/4 OASIS (OR 3.63; 95% CI 1.35-9.76) and the odds of poor QoL for the domain of 'Personal Relationships' was higher for women with an 'unclassified' OASIS (OR 4.58; 95% CI 1.22-17.23) OASIS in comparison to women who had a 3A OASIS. The odds of poor QoL for the domain of 'General Health Perception' were higher in women with a longer time period in years between sustaining the OASIS and longer term questionnaire completion (OR 1.20; 95% CI 0.17-26.90). The characteristics of age when OASIS was sustained, type of OASIS repair, mode of birth in which the OASIS was sustained in comparison to spontaneous vaginal birth and birthweight were not found to have significant negative or positive association with any of the nine QoL domains. For the QoL domain of 'Severity Measure' there were no associations with any of the independent characteristics.

Table 3.15 Multivariate analysis of the association between short-term bowel function at initial hospital clinic review following OASIS, maternal, intrapartum, OASIS and neonatal characteristics and long-term QoL.

Characteristic (n/294)		MHQ QoL domain								
		General Health Perception			Incontinence Impact			Role Limitations		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at initial hospital clinic review										
Faecal urgency										
Never	(224)		Reference			Reference			Reference	
Sometimes	(41)	2.08	(0.86-5.05)	0.105	2.45	(1.08-5.58)	*0.032*	0.95	(0.40-2.23)	0.903
Frequently	(29)	0.59	(0.24-1.49)	0.267	2.73	(0.98-7.63)	0.055	1.94	(0.59-6.42)	0.276
Flatus control										
Good	(235)		Reference			Reference			Reference	
Variable	(45)	0.94	(0.44-2.00)	0.867	0.98	(0.47-2.05)	0.952	0.96	(0.42-2.18)	0.923
Poor	(14)	1.29	(0.33-1.49)	0.717	2.92	(0.55-15.4)	0.208	3.22	(0.37-28.12)	0.290
Maternal characteristics										
Age at OASIS		0.97	(0.91-1.02)	0.224	0.97	(0.92-1.02)	0.232	1.02	(0.96-1.08)	0.564
Years between OASIS and questionnaire completion		1.20	(1.05-1.37)	*0.010*	0.98	(0.87-1.12)	0.767	1.05	(0.90-1.22)	0.571
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(155)	2.38	(0.77-7.35)	0.133	1.31	(0.49-3.56)	0.591	1.16	(0.38-3.56)	0.794
≥ 3	(49)	2.35	(0.62-8.85)	0.208	1.26	(0.37-4.29)	0.709	1.03	(0.26-4.04)	0.972
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal [¥]	(108)	0.35	(0.44-2.00)	0.075	0.60	(0.22-1.64)	0.316	0.79	(0.25-2.46)	0.683

Caesarean section only	(66)	0.18	(0.06-0.60)	*0.005*	0.54	(0.19-1.54)	0.188	0.84	(0.26-2.77)	0.780
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(23)	1.05	(0.40-2.76)	0.919	2.23	(0.80-6.27)	0.127	1.10	(0.36-3.34)	0.867
Low/unspecified forceps	(57)	1.58	(0.78-3.18)	0.203	1.16	(0.60-2.26)	0.663	0.81	(0.38-1.70)	0.569
Rotational forceps	(30)	1.70	(0.66-4.41)	0.273	0.65	(0.26-1.63	0.357	0.57	(0.21-1.51)	0.259
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(110)	1.12	(0.61-2.09)	0.711	1.07	(0.59-1.95)	0.832	1.37	(0.72-2.60)	0.342
3C/4	(54)	1.06	(0.50-2.25)	0.887	0.86	(0.41-1.80)	0.688	3.63	(1.35-9.76)	*0.011*
Unspecified	(20)	0.94	(0.29-2.98)	0.911	1.15	(0.36-3.68)	0.810	1.87	(0.49-7.14)	0.357
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.83	(0.42-1.61)	0.576	0.64	(0.34-1.22)	0.174	0.92	(0.45-1.88)	0.818
Unspecified	(97)	0.49	(0.23-1.05)	0.065	1.21	(0.57-2.56)	0.626	0.90	(0.39-2.08)	0.807
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.856	1.00	(1.00-1.00)	0.912	1.00	(1.00-1.00)	0.898

Characteristic (n)		**Physical Limitations**			**Social Limitations**			**Personal Relationships**		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at initial hospital review										
Faecal urgency										
None	(224)		Reference			Reference			Reference	
Sometimes	(41)	2.61	(1.15-5.97)	*0.023*	3.68	(1.53-8.84)	*0.004*	1.41	(0.57-3.52)	0.462
Frequently	(29)	1.79	(0.69-4.63)	0.228	2.57	(0.92-7.13)	0.070	1.25	(0.39-4.01)	0.704
Flatus control										
Good	(235)								Reference	

Variable	(45)	0.63	(0.27-1.47)	0.281	0.80	(0.32-2.03)	0.639	0.88	(0.36-2.18)	0.781
Poor	(14)	2.76	(0.76-10.05)	0.124	3.05	(0.84-11.06)	0.090	4.58	(1.22-17.23)	*0.024*
Maternal characteristics										
Age at OASIS		0.98	(0.93-1.04)	0.580	0.99	(0.93-1.06)	0.794	0.99	(0.93-1.06)	0.809
Years between OASIS and questionnaire completion		0.94	(0.82-1.08)	0.389	0.99	(0.85-1.16)	0.943	0.89	(0.76-1.04)	0.143
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(155)	1.49	(0.55-4.06)	0.433	2.24	(0.76-6.22)	0.143	2.04	(0.72-5.81)	0.181
≥ 3	(49)	2.01	(0.57-7.14)	0.279	2.74	(0.69-10.88)	0.152	1.59	(0.41-6.24)	0.506
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal [¥]	(108)	0.47	(0.16-1.37)	0.165	0.43	(0.14-1.36)	0.151	0.67	(0.23-1.99)	0.473
Caesarean section only	(66)	0.53	(0.18-1.60)	0.263	0.50	(0.15-1.64)	0.253	0.34	(0.10-1.15)	0.082
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(23)	2.57	(0.97-6.81)	0.057	1.50	(0.48-4.70)	0.491	1.13	(0.38-3.36)	0.823
Low/unspecified forceps	(57)	1.28	(0.62-2.65)	0.501	0.89	(0.39-2.03)	0.788	0.55	(0.23-1.33)	0.186
Rotational forceps	(30)	0.62	(0.21-1.83)	0.383	0.46	(0.11-1.82)	0.265	0.42	(0.12-1.43)	0.164
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(110)	1.22	(0.61-2.43)	0.579	1.15	(0.53-2.52)	0.727	1.10	(0.51-2.35)	0.814
3C/4	(54)	1.24	(0.53-2.91)	0.616	1.27	(0.49-3.27)	0.624	1.56	(0.64-3.79)	0.324
Unspecified	(20)	2.08	(0.63-6.88)	0.230	1.54	(0.40-5.92)	0.530	4.52	(1.22-16.82)	*0.024*
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.52	(0.24-1.10)	0.085	0.85	(0.37-1.97)	0.701	0.69	(0.31-1.54)	0.364

Unspecified	(97)	1.08	(0.47-2.52)	0.851	1.23	(0.47-3.25)	0.678	1.10	(0.44-2.75)	0.841
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.694	1.00	(1.00-1.00)	0.133	1.00	(1.00-1.00)	0.727
Characteristic (n)		**Emotions**			**Sleep/Energy**			**Severity Measure**		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at initial hospital review										
Faecal urgency										
None	(224)		Reference			Reference			Reference	
Sometimes	(41)	1.23	(0.56-2.71)	0.604	1.55	(0.64-3.76)	0.328	1.77	(0.81-3.85)	0.154
Frequently	(29)	1.11	(0.44-2.80)	0.818	1.26	(0.43-3.72)	0.678	0.76	(0.31-1.90)	0.564
Flatus control										
Good	(235)		Reference			Reference			Reference	
Variable	(45)	1.15	(0.56-2.36)	0.711	0.84	(0.34-2.04)	0.693	1.22	(0.60-2.49)	0.590
Poor	(14)	6.56	(1.31-32.88)	*0.022*	1.70	(0.45-6.40)	0.432	4.70	(0.93-23.67)	0.061
Maternal characteristics										
Age at OASIS		0.99	(0.94-1.04)	0.630	0.96	(0.90-1.02)	0.170	1.00	(0.96-1.06)	0.721
Years between OASIS and questionnaire completion		1.07	(0.94-1.22)	0.298	1.04	(0.90-1.20)	0.631	1.03	(0.91-1.17)	0.653
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(155)	1.02	(0.40-2.62)	0.971	3.34	(1.20-9.33)	*0.021*	1.50	(0.58-3.90)	0.407
≥ 3	(49)	0.89	(0.27-2.90)	0.840	4.63	(1.28-16.76)	*0.020*	1.65	(0.50-5.38)	0.410
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal [¥]	(108)	0.45	(0.17-1.20)	0.109	0.44	(0.16-1.26)	0.126	0.49	(0.18-1.31)	0.154
Caesarean section only	(66)	0.40	(0.14-1.13)	0.083	0.22	(0.07-0.68)	*0.009*	0.49	(0.18-1.35)	0.167

Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(23)	1.08	(0.42-2.78)	0.866	2.14	(0.75-6.08)	0.154	2.04	(0.78-5.36)	0.146
Low/unspecified forceps	(57)	1.77	(0.92-3.42)	0.090	1.35	(0.64-2.85)	0.427	1.08	(0.56-2.07)	0.814
Rotational forceps	(30)	0.82	(0.32-2.07)	0.667	0.80	(0.23-2.76)	0.722	1.09	(0.44-2.68)	0.860
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(110)	1.47	(0.80-2.69)	0.212	0.93	(0.46-1.91)	0.849	0.92	(0.51-1.65)	0.768
3C/4	(54)	1.44	(0.54-2.43)	0.726	1.37	(0.59-3.17)	0.460	1.24	(0.60-2.56)	0.566
Unspecified	(20)	2.08	(0.67-6.48)	0.208	0.85	(0.23-3.12)	0.805	2.39	(0.76-7.53)	0.136
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.62	(0.32-1.20)	0.154	1.80	(0.84-3.87)	0.133	0.80	(0.43-1.51)	0.495
Unspecified	(97)	1.13	(0.53-2.41)	0.752	1.31	(0.52-3.26)	0.568	0.86	(0.41-1.79)	0.678
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.085	1.00	(1.00-1.00)	0.724	1.00	(1.00-1.00)	0.396

¥ includes four women with a combination of vaginal and caesarean section mode of post OASIS births

3.9.9 Multivariate analysis of the association between long-term bowel function, maternal, intrapartum, OASIS and neonatal characteristics and long-term QoL.

As well as looking at short-term bowel symptoms as possible contributory characteristics for an impact on long-term QoL (section 3.9.8), the effect of long-term bowel symptoms was also investigated. Table 3.16 shows the multivariate analysis investigating the association between long-term bowel function and maternal, intrapartum, OASIS and each of the nine MHQ QoL domains. For many of the QoL domains, bowel symptoms not surprisingly had a negative impact. The odds of poor QoL for the five MHQ QoL domains of 'Incontinence Impact' (OR 4.36; 95% CI 2.17-8.75), 'Role Limitations' (OR 2.02; 95% CI 1.01-4.05), 'Physical Limitations' (OR 3.54; 95% CI 1.23-10.13), and 'Emotions' (OR 2.74; 95% CI 1.24-6.05) and 'Severity Measure' (OR 2.87; 95% CI 1.35-6.13) were significantly higher in women who experienced faecal urgency ('Occasionally/Sometimes') compared to those without this symptom. The odds of poor QoL for the seven domains of 'General Health Perception' (OR 5.74; 95% CI 1.31-25.27), 'Physical Limitations' (OR 12.75; 95% CI 3.00-54.24), 'Social Limitations' (OR 13.70; 95% CI 3.10-60.59), 'Personal Relationships' (OR 8.79; 95% CI 2.13-36.25), 'Emotions' (OR 14.22; 95% CI 2.59-78.06), 'Sleep/Energy' (OR 11.53; 95% CI 2.76-48.21) and 'Severity Measure' (OR 6.11; 95% CI 1.30-28.72) were significantly higher in women who experienced faecal urgency ('Most/All of the time') compared with women with no long-term faecal urgency. There were not enough events of this characteristic to allow inclusion in multivariate analysis of the two remaining QoL domains. The odds of poor QoL for the QoL domains of 'Personal Relationships' (OR 2.40; 95% CI 1.18-4.87), 'Sleep/Emotion' (OR 2.21; 95% CI 1.10-4.43) and 'Severity Measure' (OR 2.94; 95%

CI 1.57-5.51) were significantly higher in women who had long-term difficulty wiping clean ('Occasionally/Sometimes') compared with women who did not have this. The odds of poor QoL for the three QoL domains of 'Incontinence Impact' (OR 2.66; 95% CI 1.42-4.97), 'Emotions' (OR3.81; 95% CI 1.90-7.65) and 'Severity Measure' (OR 2.34; 95% CI 1.20-4.57) were significantly higher for women who experienced poor control of flatus ('Occasionally/Sometimes') compared to women who had good control of flatus. The odds of poor QoL for the QoL domains of 'Incontinence Impact' (OR 7.14; 95% CI 2.02-25.15), 'Personal Relationships' (OR 2.98; 95% CI 1.03-8.57), 'Social Limitations' (OR 3.55; 95% CI 1.12-11.31), 'Emotions' (OR 8.20; 95% CI 2.83-23.79) and 'Severity Measure' (OR 5.56; 95% CI 1.74-17.78) were higher for women who had long-term poor control of flatus (' Most/All of the time') when compared to women who had good flatal control. The odds of poor QoL for the six QoL domains of 'Role Limitations' (OR 2.47; 95% CI 1.23-4.96), 'Physical Limitations' (OR 3.18; 95% CI 1.67-6.06), 'Social Limitations' (OR 3.24; 95% CI 1.55-6.75), 'Emotions' (OR 2.16; 95% CI 1.12-3.99), 'Sleep/Energy' (OR 2.15; 95% CI 1.11-4.17) and 'Severity Measure' (OR 3.98; 95% CI 2.09-7.57) was higher for women who had long-term faecal leakage compared to those who did not.

When considering any association between maternal characteristics and long-term bowel function, the odds of poor QoL for the domain of 'General Health Perception' were higher in women with a longer time period in years between sustaining the OASIS and longer term questionnaire completion (OR 1.19; 95% CI 1.04-1.37). With regard to parity, the odds of poor QoL for the 'Sleep/Energy' domain were significantly higher in women with a parity of two (OR 3.16; 95% CI 1.02-9.77), and

women having a total parity of three or more (OR 4.50; 95% CI 1.11-18.18) compared with women with a total parity of one. For mode of birth(s) following OASIS, the odds of poor 'General Health Perception' QoL (OR 0.18; 95% CI 0.05-0.60) were significantly lower for women that had a subsequent birth(s) by caesarean section compared with women who had no subsequent births. Regarding extent of the OASIS, the odds of poor QoL for the domain of 'Role Limitations' were higher in women with a 3C/4 OASIS (OR 4.25; 95% CI 1.52-11.93) in comparison to women who had a 3A OASIS. For the method of OASIS repair, the odds of poor QoL for the domain of 'General Health Perception' were lower for women where the repair method was unspecified (OR 0.40; 95% CI 0.18-0.88) when compared to a known 'end-to-end' repair technique. The age of the mother when OASIS was sustained, mode of birth in which the OASIS was sustained and birthweight were not found to have any associations with any of the nine QoL domains.

Due to the low number of events, the results of this multivariate analysis need to be interpreted with caution as some of the confidence intervals are large and therefore precision of the estimates is low.

Table 3.15 Multivariate analysis of the association between long-term bowel function following OASIS, maternal, intrapartum, OASIS and neonatal characteristics and long-term QoL.

Characteristic (n/294)		MHQ QoL domain: General Health Perception OR	95% CI	*p*	Incontinence Impact OR	95% CI	*p*	Role Limitations OR	95% CI	*p*
Bowel symptoms at questionnaire completion										
Faecal urgency										
Never	(69)		Reference			Reference			Reference	
Occasionally/Sometimes	(201)	1.67	(0.89-3.14)	0.112	4.36	(2.17-8.75)	*<0.001*	2.02	(1.01-4.05)	*0.047*
Most/All of the time	(24)	5.74	(1.31-25.27)	*0.021*	1	-----	---	1	----	---
Poor flatus control										
Never	(99)		Reference			Reference			Reference	
Occasionally/Sometimes	(151)	0.90	(0.50-1.63)	0.574	2.66	(1.42-4.97)	*0.002*	0.47	(0.24-0.93)	*0.030*
Most/All of the time	(44)	1.03	(0.38-2.77)	0.331	7.14	(2.02-25.15)	*0.002*	0.55	(0.17-1.80)	0.319
Difficulty wiping										
Never	(168)		Reference			Reference			Reference	
Occasionally/Sometimes	(103)	1.18	(0.66-2.12)	0.729	0.97	(0.52-1.82)	0.929	0.77	(0.40-1.48)	0.426
Most/All of the time	(23)	1.76	(0.56-5.54)	0.953	2.99	(0.59-15.05)	0.185	0.95	(0.26-3.57)	0.942
Any faecal leakage										
Absent	(189)		Reference			Reference			Reference	
Present	(105)	1.24	(0.69-2.22)	0.466	1.77	(0.93-3.38)	0.081	2.47	(1.23-4.96)	*0.011*
Maternal characteristics										
Age at OASIS		0.97	(0.91-1.02)	0.233	0.97	(0.91-1.03)	0.280	1.04	(0.98-1.11)	0.206

Years between OASIS and questionnaire completion		1.19	(1.04-1.37)	*0.011*	0.97	(0.84-1.13)	0.729	1.05	(0.90-1.23)	0.514
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(155)	2.66	(0.85-8.34)	0.094	1.35	(0.43-4.21)	0.604	1.21	(0.38-3.93)	0.747
≥ 3	(49)	2.62	(0.67-10.28)	0.166	1.05	(0.26-4.33)	0.944	1.03	(0.24-4.37)	0.965
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal [¥]	(108)	0.37	(0.12-1.18)	0.093	0.71	(0.22-2.25)	0.555	0.72	(0.22-2.37)	0.596
Caesarean section only	(66)	0.18	(0.05-0.60)	*0.006*	0.82	(0.24-2.84)	0.754	0.99	(0.28-3.49)	0.985
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(23)	0.94	(0.35-2.54)	0.909	1.85	(0.57-6.03)	0.309	0.93	(0.30-2.90)	0.901
Low/unspecified forceps	(57)	1.42	(0.71-2.87)	0.323	0.97	(0.46-2.06)	0.934	0.75	(0.34-1.62)	0.459
Rotational forceps	(30)	1.86	(0.70-5.00)	0.219	0.79	(0.26-2.36)	0.670	0.46	(0.16-1.32)	0.149
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(110)	0.95	(0.50-1.79)	0.871	0.75	(0.38-1.49)	0.408	1.52	(0.77-3.03)	0.229
3C/4	(54)	0.83	(0.38-1.79)	0.633	0.51	(0.21-1.19)	0.120	4.25	(0.52-11.93)	*0.006*
Unspecified	(20)	0.78	(0.23-2.60)	0.682	0.66	(0.17-2.55)	0.544	2.11	(0.51-8.82)	0.306
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.93	(0.48-1.81)	0.837	0.54	(0.26-1.13)	0.102	0.94	(0.45-1.96)	0.864
Unspecified	(97)	0.40	(0.18-0.88)	*0.022*	1.05	(0.44-2.52)	0.907	0.93	(0.39-2.24)	0.875
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.739	1.00	(1.00-1.00)	0.444	1.00	(1.00-1.00)	0.819

Characteristic (n)		Physical Limitations			Social Limitations			Personal Relationships		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*P*
Bowel symptoms at questionnaire completion										
Faecal urgency										
Never	(69)		Reference			Reference			Reference	
Occasionally/Sometimes	(201)	3.54	(1.23-10.13)	*0.019*	1.67	(0.56-4.97)	0.357	2.86	(1.00-8.22)	0.051
Most/All of the time	(24)	12.75	(3.00-54.24)	*0.001*	13.70	(3.10-60.59)	*0.001*	8.79	(2.13-36.25)	*0.003*
Poor flatus control										
Never	(99)		Reference			Reference			Reference	
Occasionally/Sometimes	(151)	2.11	(0.94-4.71)	0.070	1.41	(0.56-3.55)	0.461	1.23	(0.53-2.82)	0.629
Most/All of the time	(44)	2.98	(1.03-8.57)	*0.043*	3.55	(1.12-11.31)	*0.032*	2.26	(0.76-6.72)	0.141
Difficulty wiping										
Never	(168)		Reference			Reference			Reference	
Occasionally/Sometimes	(103)	1.76	(0.91-3.44)	0.096	2.03	(0.95-4.34)	0.067	2.40	(1.18-4.87)	*0.015*
Most/All of the time	(23)	1.08	(0.35-3.32)	0.900	0.66	(0.17-2.61)	0.558	1.06	(0.31-3.63)	0.923
Any faecal leakage										
Absent	(189)		Reference			Reference			Reference	
Present	(105)	3.18	(1.67-6.06)	*<0.001*	3.23	(1.55-6.75)	*0.002*	1.89	(0.97-3.70)	0.062
Maternal characteristics										
Age at OASIS		1.00	(0.93-1.06)	0.888	1.04	(0.96-1.12)	0.353	1.01	(0.94-1.08)	0.774
Years between OASIS and questionnaire completion		0.91	(0.78-1.06)	0.237	0.94	(0.79-1.12)	0.478	0.85	(0.72-1.01)	0.068
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(155)	1.51	(0.50-4.54)	0.465	2.03	(0.63-6.48)	0.234	1.89	(0.64-5.58)	0.247
≥ 3	(49)	2.09	(0.54-8.20)	0.289	3.02	(0.68-13.38)	0.146	1.52	(0.37-6.24)	0.563
Post-OASIS births										
None	(120)		Reference			Reference			Reference	

Vaginal [¥]	(108)	0.58	(0.18-1.82)	0.348	0.44	(0.13-1.47)	0.182	0.86	(0.28-2.63)	0.791
Caesarean section only	(66)	0.90	(0.26-3.05)	0.852	0.86	(0.23-3.19)	0.823	0.43	(0.12-1.55)	0.196
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(23)	1.85	(0.63-5.40)	0.264	0.85	(0.24-3.06)	0.806	0.83	(0.26-2.65)	0.757
Low/unspecified forceps	(57)	1.06	(0.48-2.36)	0.890	0.82	(0.33-2.06)	0.669	0.48	(0.19-1.20)	0.118
Rotational forceps	(30)	0.44	(0.13-1.52)	0.193	0.25	(0.05-1.21)	0.086	0.29	(0.07-1.10)	0.069
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(110)	0.93	(0.43-1.98)	0.842	0.86	(0.36-2.05)	0.727	0.80	(0.35-1.84)	0.605
3C/4	(54)	0.77	(0.30-1.99)	0.595	0.70	(0.24-2.02)	0.508	1.16	(0.45-3.00)	0.760
Unspecified	(20)	1.11	(0.28-4.45)	0.881	0.60	(0.11-3.19)	0.552	3.22	(0.73-14.16)	0.121
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.48	(0.21-1.08)	0.075	0.79	(0.31-1.97)	0.610	0.65	(0.28-1.53)	0.326
Unspecified	(97)	0.97	(0.39-2.45)	0.949	1.02	(0.36-2.94)	0.965	0.94	(0.35-2.51)	0.903
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.983	1.00	(1.00-1.00)	0.253	1.00	(1.00-1.00)	0.940

Characteristic (n)		**Emotions**			**Sleep/Energy**			**Severity Measures**		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at questionnaire completion										
Faecal urgency										
Never	(69)		Reference			Reference			Reference	
Occasionally/Sometimes	(201)	2.74	(1.24-6.05)	*0.013*	2.35	(0.86-6.42)	0.095	2.87	(1.35-6.13)	*0.006*
Most/All of the time	(24)	14.22	(2.59-78.06)	*0.002*	11.53	(2.76-48.21)	*0.001*	6.11	(1.30-28.72)	*0.022*

Poor flatus control										
Never	(99)		Reference			Reference			Reference	
Occasionally/Sometimes	(151)	3.81	(1.90-7.65)	*<0.001*	1.69	(0.74-3.90)	0.216	2.34	(1.20-4.57)	*0.013*
Most/All of the time	(44)	8.20	(2.83-23.79)	*<0.001*	2.36	(0.77-7.21)	0.131	5.56	(1.74-17.78)	*0.004*
Difficulty wiping										
Never	(168)		Reference			Reference			Reference	
Occasionally/Sometimes	(103)	1.04	(0.55-1.96)	0.906	2.21	(1.10-4.43)	*0.026*	2.94	(1.57-5.51)	*0.001*
Most/All of the time	(23)	2.74	(0.80-9.41)	0.110	0.84	(0.24-2.94)	0.784	8.88	(1.76-44.66)	*0.008*
Any faecal leakage										
Absent	(189)		Reference			Reference			Reference	
Present	(105)	2.16	(1.17-4.00)	*0.014*	2.15	(1.11-4.17)	*0.024*	3.98	(2.09-7.57)	*<0.001*
Maternal characteristics										
Age at OASIS		0.99	(0.93-1.05)	0.665	0.96	(0.89-1.02)	0.193	1.00	(0.94-1.07)	0.944
Years between OASIS and questionnaire completion		1.07	(0.92-1.23)	0.373	1.01	(0.86-1.18)	0.912	1.03	(0.89-1.20)	0.700
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(155)	0.87	(0.31-2.50)	0.801	3.16	(1.02-9.77)	*0.046*	1.59	(0.52-4.94)	0.419
≥ 3	(49)	0.56	(0.15-2.14)	0.398	4.50	(1.11-18.18)	*0.035*	1.36	(0.34-5.51)	0.663
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal [¥]	(108)	0.53	(0.18-1.59)	0.256	0.63	(0.20-1.97)	0.431	0.60	(0.19-1.88)	0.385
Caesarean section only	(66)	0.57	(0.17-1.86)	0.351	0.31	(0.09-1.13)	0.075	0.71	(0.20-2.47)	0.589
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	

Kiwi	(23)	0.95	(0.33-2.73)	0.924	1.92	(0.62-6.00)	0.260	1.59	(0.51-4.91)	0.423
Low/unspecified forceps	(57)	1.48	(0.71-3.11)	0.298	1.14	(0.50-2.57)	0.758	0.75	(0.34-1.65)	0.478
Rotational forceps	(30)	0.85	(0.28-2.60)	0.782	0.64	(0.16-2.57)	0.533	1.07	(0.33-3.42)	0.911
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(110)	1.21	(0.61-2.41)	0.583	0.67	(0.30-1.50)	0.329	0.66	(0.32-1.34)	0.247
3C/4	(54)	0.86	(0.37-2.04)	0.740	0.89	(0.35-2.23)	0.799	0.77	(0.31-1.88)	0.560
Unspecified	(20)	1.50	(0.39-5.70)	0.552	0.39	(0.09-1.80)	0.228	1.51	(0.38-6.10)	0.560
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.52	(0.25-1.09)	0.083	2.12	(0.92-4.88)	0.077	0.76	(0.36-1.61)	0.474
Unspecified	(97)	1.10	(0.46-2.64)	0.826	1.29	(0.47-3.51)	0.621	0.63	(0.27-1.51)	0.302
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.117	1.00	(1.00-1.00)	0.928	1.00	(1.00-1.00)	0.508

¥ includes four women with a combination of vaginal and caesarean section mode of post OASIS births

3.9.10 Analysis of data for women sustaining OASIS following introduction of RCOG Green-top Guideline

As discussed in section 1.1 in July 2001 the RCOG published the first evidence based guidelines for the structured recognition and repair of OASIS (15). The local clinical guidelines for repair of OASIS at the NHS Trust in which the study was undertaken were updated to incorporate these RCOG recommendations immediately following publication. Monthly audits are undertaken in the Trust for all local guidelines to ensure compliance and adhere to national clinical negligence legislation. Consequently data from women in the study who sustained OASIS prior to the introduction of the RCOG green top guideline may not be representative of those in whom OASIS was identified and repaired following implementation of these recommendations. Therefore, in order to allow time for the RCOG green-top guideline evidence based recommendations to be embedded into clinical practice within the Trust sensitivity analyses were conducted removing any women who sustained OASIS prior to January 2002, to see if there was a difference in predictor characteristics for bowel symptoms and an effect on QoL once OASIS repair was undertaken using the best practice technique.

There were only five women who had sustained OASIS before January 2002. Analyses were completed omitting these five women (see Appendices 3.2, 3.3 and 3.4) but findings were similar to those in which they were included.

3.10 Discussion

This study followed a large group of women who had an obstetric anal sphincter injury from 0.82 to 14.10 years with a mean of 5.33 years. There are very few previous studies that are as large and have followed women for anything other than relatively short periods. This study showed that the incidence of faecal urgency at baseline contact at three months post OASIS was 23.8%. This is similar to that reported by Williams et al (106) who, in an RCT of 89 women undertaken to compare the outcomes of an overlap repair method versus an end-to-end repair, found an incidence of faecal urgency at three months post OASIS of 25%. Reid et al (2014) (81), from their follow-up study of 344 women found that at nine weeks following the OASIS, a slightly higher incidence of faecal urgency of 32.2%. The study undertaken in this thesis has also shown that 20.1% of women had poor control of flatus at three months following the OASIS. This is similar to that reported by Fernando et al (2006) (109), who, in a small RCT undertaken to compare OASIS repair methods, reported an incidence of poor control of flatus of 20% for the 60 women reviewed at three months postpartum. However, their reported incidence of faecal urgency (38.3%) and faecal incontinence (19.3%) were higher than that found for these symptoms in this study which were 23.8% and 6.7% respectively. Another small study to compare OASIS repair methods (Garcia et al (2005)) (110), reported a comparable incidence of poor control of flatus (27%) for the 26 women reviewed at a mean of three months postpartum [± 2.5 months], however, faecal incontinence was much higher (42%). Tetzschner et al (1996) (86), in a study of 72 women undertaken to assess the long-term impact of OASIS on bowel and urinary function found much lower incidences of both poor control of flatus and anal incontinence at

14% and 4% respectively. In an observational study of 53 women undertaken to establish the incidence of anal and urinary incontinence in women following their first vaginal birth, Andrews et al (2013) (105), also found a much lower incidence of poor control of flatus (2.8%) and anal incontinence (3.7%) for women with previous OASIS when assessed at seven weeks postnatal. A possible explanation for the variations in reported incidences of bowel symptoms within the published literature is likely to be due to the small sample sizes on which some of the study findings are based, the use of alternative bowel symptom questionnaires to capture the data that makes comparison of symptoms difficult and possible bias from randomisation techniques and attrition rates at follow-up.

The findings from this study also demonstrate an increase in the incidence of poor control of flatus, faecal urgency and faecal leakage between initial hospital clinical review at three months post OASIS and at long-term follow-up review of a mean time period of 5.82 years (SD ±3.37 years). At long-term follow-up over two thirds (66.3%) had poor control of flatus, over three quarters of the women (76.5%) had faecal urgency and over a third of women (35.7%) reported any type of faecal leakage. These incidences are both supported and refuted by findings from published studies with comparable mean follow-up time points of four to six years after the OASIS was sustained (76, 83, 102, 105, 111-113). With regard to long-term poor control of flatus, in a small study of 40 women with OASIS at a mean follow-up time of 5 years post OASIS (SD ± 2.3 years), Vischer et al (2014) (83) reported a similar incidence of 63%. Palm et al (2012) (111) , also reported a similar incidence of 70%, from their larger study of 219 women with a mean follow-up time since the

OASIS of 5.8 years (range 1.3-9 years). However, several studies have reported the incidence of long-term poor control of flatus for women with previous OASIS to be lower. Nordenstam et al (2009) (76) reported a slightly lower incidence of poor control of flatus of 55% for women with previous OASIS when reviewed at a mean time period of five years following the injury. However, although the follow-up time period was similar the cohort of women with an OASIS that were included in their study was only 29 women. In a larger study by Wagenius et al (2003) (102) of 186 women with previous OASIS, at a mean follow-up time of four years post OASIS, the reported incidence of poor control of flatus was 33%. Pollack et al (2004) (113) reported a slightly lower incidence of poor control of flatus of 47% for women with previous OASIS when reviewed at a mean time period of five years following the injury. Although their follow-up time period was similar the cohort of women with an OASIS that were included in their study was only 36 women. Andrews et al (2013) (105), reported a much lower incidence of poor control of flatus of 12% for women with previous OASIS when reviewed at a mean time period of four years following the injury. Nevertheless, their study included only 25 women with previous OASIS at the four year follow-up time point. Regarding faecal urgency in the long-term following OASIS and faecal leakage during sexual intercourse, the published literature of these bowel symptoms at a comparable follow-up time period is very limited. Although their incidence of poor control of flatus was similar to that found in this study, Palm et al (2012) (111) reported a much lower incidence of faecal urgency and of faecal leakage during sexual intercourse of only 19.5% and 1.4% respectively, as compared to the incidences found in this study of 76.5% and 8.2%, and with a sample size and follow-up period being similar to this study. With regard

to long-term faecal leakage there are no published studies with a comparable follow-up time period that gave a similar incidence to that found in this study (35.7%). Two studies gave a higher incidence for long-term faecal leakage for women who have sustained an OASIS. In a small study of 41 women with previous OASIS, Kumar et al (2010) (112), reported an incidence of faecal incontinence in 46% of women at five year follow-up. Nordenstam et al (2009) (76) reported a slightly higher incidence of faecal incontinence of 55% for women with previous OASIS when reviewed at a mean time period of five years following the injury. However, the cohort of women with an OASIS that were included in their study was only 29 women. Three studies gave a lower incidence for faecal leakage for women who have sustained an OASIS at a similar long-term time period to this study. Wagenius et al (2003) (102) reported an incidence of faecal incontinence of 25% from their study of 186 women with previous OASIS, at a mean follow-up time of four years post OASIS. Andrews et al (2013) (105), reported an incidence of faecal incontinence of 16% for women with previous OASIS when reviewed at a mean time period of four years following the injury. However, their study included only 25 women with previous OASIS at the four year follow-up time point. Pollack et al (2004) (113) reported a slightly lower incidence of faecal incontinence of 11% for women with previous OASIS when reviewed at a mean time period of five years following the injury. However, although the follow-up time period was similar the cohort of women with an OASIS that were included in their study was only 36 women. As with the findings for the incidence of short-term bowel symptoms following OASIS, the variations in reported incidences of long-term bowel symptoms within the published literature could be due to the small sample sizes on which some of the study findings are based, the use of alternative

bowel symptom questionnaires to capture the data that makes comparison of symptoms difficult and possible self-selection bias.

This study has also identified, through multivariate logistic regression modelling, the type and severity of bowel symptoms at the short-term, maternal, intrapartum, sphincter injury and neonatal characteristics that were significantly associated with long-term bowel symptoms and QoL. For women in this study 'Variable' control of flatus following the OASIS was significantly associated with long-term 'poor' control of flatus but was not significantly associated with any of the MHQ QoL domains in the longer term. 'Poor' control of flatus in the short-term was not significantly associated with poor flatal control in the longer term but it did have a significant negative association with two MHQ QoL domains. Faecal urgency experienced 'sometimes' in the three months postpartum was significantly associated with long-term faecal urgency and passive faecal leakage. As demonstrated in the systematic review detailed in chapter two, there are a limited number of published other studies that have investigated bowel symptoms in the postnatal period following OASIS as possible contributory factors for long-term bowel symptoms and QoL. Some published studies have investigated the impact of OASIS on longer-term bowel function, but have not undertaken an initial survey of bowel symptoms in the postnatal period (72-75, 77-79, 82, 102). Whilst other studies have undertaken an initial postnatal bowel symptom assessment but have not used this data to investigate whether these short term symptoms were associated with long-term bowel symptoms, but rather as a measure of change in incidence or comparison with women who did not sustain an OASIS (76, 81, 84, 90). In a study undertaken to

assess the influence of various risk factors on long-term AI in women with a previous OASIS, Bek et al (1992) (80) found that transient AI (up to 9 months following the OASIS) after a 3C/4 OASIS was significantly associated with the development of long-term permanent AI after the next birth (OR 23; 95% CI 3.7-150). However, the study sample included only 56 women and the incidence of AI following the OASIS was taken from a retrospective postal survey that was sent to the women two to 12 years following the birth when the OASIS occurred. Therefore, the findings must be interpreted with caution due to the possibility of recall bias.

It is worth noting that in this study the milder degrees of flatus control (variable) and urgency (sometimes) in the short-term were found to be significantly associated with long-term bowel symptoms and a negative impact on QoL. This could be due to the lower number of women experiencing the more severe symptoms of faecal urgency 'frequently' (29/294, 9.9%) and control of flatus 'poor' (14/294, 4.8%) in this cohort. However, this finding serves to highlight the importance of recognition of the presence of bowel symptoms irrespective of their frequency or severity and reinforces the necessity to recognise flatus control and the ability to defer a bowel motion as fundamental aspects of bowel function and incontinence (52).

Interestingly, women in this thesis study who had birth(s) subsequent to that in which the OASIS was sustained, either by vaginal birth or by caesarean section, were not at significantly increased odds of any faecal leakage when compared to the women who did not have subsequent births. This is in contrast to findings from a study of 117 women, where Poen et al (82), demonstrated a significantly higher incidence of reported symptoms of AI in women with previous OASIS who had a subsequent birth

versus those who did not (RR 1.6; 95%CI 1.1-2.5; *p*=0.025). Similarly, Visscher et al (2014) (83), found that faecal incontinence was increased in women with previous OASIS with a subsequent birth relative to those without (p=0.008) but this was a very small study of 66 women and it excluded all women who were asymptomatic following the OASIS. However, this thesis study also found an improvement in ability to control flatus in the longer term for women having subsequent births by caesarean section compared to women with no subsequent birth(s). This finding is supported by that from Scheer et al (2009) (44) who, in a small prospective follow-up study of 44 women, found improvements in flatus incontinence for the nine women who underwent a recommended caesarean section. Both this study and that of Scheer et al (2009) used the RCOG recommendation that women who were symptomatic were recommended a caesarean section. It would therefore be reasonable to postulate that this improvement is not due to the mode of caesarean birth 'per se', but may be influenced by women learning to cope with/adapt to symptoms of bowel symptoms in the longer term or an actual improvement because of management interventions like dietary changes or physiotherapy; an association and rationale that was also found and suggested by Bondili et al (2011) (88).

This study also found that a 3B OASIS was significantly associated with long-term faecal urgency when compared to the reference standard of a 3A OASIS. This finding is supported by that from De Leeuw et al (2001) (77) who, in a prospective follow-up study of 125 women with previous OASIS found a significantly increased incidence of AI in women who had sustained either a 3B or 4th degree OASIS. However, several studies have found that the higher grade of OASIS of 3C/4 that

involve the IAS are associated with a significantly poorer bowel function outcome and this is probably due to the important role the IAS muscle plays in maintaining anal continence through its constant tonic state (83, 114, 115). Although speculative, the findings in this study that a the lesser degree of OASIS trauma of 3B may be due to incorrect under-classification of the injury at the time of repair and/or occult injury to the internal anal sphincter.

With regard to parity, a parity of two or more was not significantly associated with long-term bowel symptoms. However, there was a significant negative association with two of the MHQ QoL domains. These findings are partly supported by Huebner et al (2013) (78) who, in a retrospective study of 99 women with previous OASIS to determine obstetric variables associated with long-term faecal incontinence found no significant association between parity and faecal incontinence. This study also demonstrated increased odds for poor QoL (one domain) for women with a longer time period in years between sustaining the OASIS and follow-up questionnaire completion. Again, due to the lack of published research into the long-term impact of OASIS on QoL as highlighted in the systematic review detailed in chapter two, it is not possible to be certain about the reason for this observation, however, it is reasonable to postulate that this may be a contributory factor from age and hormonal changes.

As well as identifying short-term bowel symptoms that are significantly associated with long-term bowel symptoms and QoL, this study has also identified bowel symptoms and their corresponding severity occurring in the longer-term following OASIS that are significantly associated with long-term QoL. This study found that

the odds of poor QoL for five MHQ QoL domains were significantly higher in women who experienced faecal urgency 'Occasionally/Sometimes' compared with women with no long-term faecal urgency. The odds of poor QoL for seven of the MHQ QoL domains were significantly higher in women who experienced faecal urgency 'Most/All of the time' compared with women with no long-term faecal urgency. The odds of poor QoL for three of the MHQ QoL domains were significantly higher in women who had long-term difficulty wiping clean 'Occasionally/Sometimes' compared with women who did not have this. Whereas difficulty wiping clean experienced 'Most/All of the time' was only associated as a significant characteristic with poor QoL for one QoL domain. The odds of poor QoL for three of the QoL domains were significantly higher for women who experienced poor control of flatus 'Occasionally/Sometimes' at questionnaire completion compared to women who had good control of flatus in the long term. However, the odds for poor QoL in one QoL domain were decreased for women with poor control of flatus 'Occasionally/Sometimes' when compared to women who had good control of flatus in the long-term. The odds of poor QoL for five of the QoL domains were higher for women who had long-term poor control of flatus ' Most/All of the time' when compared to women who had good flatus control. The odds of poor QoL for six of the QoL domains were higher for women who had long-term faecal leakage when compared to those who did not. As demonstrated in the systematic review detailed in chapter two, despite QoL being an important indicator for women with previous OASIS when deciding on future pregnancy and mode, research into this area is limited and there are only ten studies that have investigated long-term QoL for women with a previous OASIS. However, within those published studies none have

used long term bowel symptom and their corresponding severity as possible contributory factors for long-term QoL.

Women with long term bowel symptoms and a parity of two or more had significantly higher odds for poor QoL for one of the MHQ QoL domains. Again, it was not possible to relate findings from this study to that produced by other groups due to the lack of published research undertaken to explore long-term QoL for women with previous OASIS. However, it is plausible to consider that this finding could be due to the associated stress and tiredness from mothering a larger family as the domain affected was 'Sleep/Energy'. This study also demonstrated increased odds for poor QoL (one domain) for women with a longer time period in years between sustaining the OASIS and follow-up questionnaire completion. Again, there is no evidence to support this finding, however, it is reasonable to suggest that this may be due to contributory factors from age and hormonal changes resultant from an increased time period since the OASIS was sustained.

3.10.1 Strengths and limitations

This study has several strengths. Of the few longer term follow up studies previously undertaken this study has one of the largest sample sizes. Prospective patient completed documentation of short-term bowel symptoms has reduced the risk of recall bias thus allowing changes in bowel function to be a more accurate reflection and not subject to over/under estimation. This study has also researched the long-term impact of sustaining an OASIS on QoL, which the systematic review undertaken in chapter one and comparison of study findings to the published

literature in section 5.1 have both shown to be areas of research that are currently lacking.

Another strength of this study is that 98.3% of the women sustained and had their OASIS repaired following the introduction of the RCOG Green-top guideline in 2001. Multivariate analyses of data from the sub-cohort of these women demonstrated very similar results to those of the full cohort. Not only does this address a limitation that was identified from the systematic review undertaken in chapter two that there is currently limited research reporting outcomes on bowel function and quality of life for women who sustained an OASIS since the evidence based standards of OASIS recognition and repair were introduced, it also means that the findings from this study on the longer term outcomes and associated characteristics can be used for the counselling of the current generation of women who have sustained an OASIS.

The main potential limitation of this study is that only 31.1% of the initial cohort responded to the questionnaire, thus the possibility of selection bias should be considered. However, the availability of routine data on all women allowed comparisons of all the characteristics of responders compared to non-responders. This demonstrated significant differences only in age and ethnicity, which are characteristics in postal study responses that are known to be a potential risk of bias and also characteristics that may not be avoided by an interview as opposed to a postal survey (116) . The other characteristics were all similar, including symptoms at initial hospital clinic review, which reduces the limitations of the low response rate. Therefore this increases the likelihood that the study findings were representative and can be generalised. Another possible limitation of this study is the use of two

different bowel symptom reporting mechanisms used to record bowel function at the initial hospital clinic review and the MHQ postal questionnaire used to capture long-term bowel function. However, this was acknowledged and in order to allow comparisons between the bowel symptoms that had been routinely recorded at initial hospital consultation review prior to the study and those captured within the study by the validated MHQ, bowel symptom frequency was appropriately matched. Also, due to the low number of events for some of the bowel symptoms, results from the multivariate analyses undertaken within this study must be interpreted with caution as some of the confidence intervals are large and therefore precision of the estimates is low. However, the findings from this study are still valid.

3.10.2 Summary

This large study adds to the limited data that is currently available on the natural history of OASIS and its relationship with long-term bowel function and related QoL and to identify any significant independent characteristics that may contribute to longer term bowel symptoms or impact on QoL, including subsequent birth.

For the cohort of women in this study, the incidence of faecal urgency at baseline was 23.8%, poor control of flatus was experienced by 20.1% of women and 6.7% of women had faecal incontinence.

At long-term follow-up with a mean of 5.82 years (±3.37) later, bowel symptoms were much more common. The proportion of women reporting faecal urgency had more than trebled (76.5%) with a similar trebling for poor flatus control (66.3%) and faecal

leakage had increased almost five-fold (35.7%). Of course, the method of ascertainment of bowel symptoms differed, as will be discussed in chapter five.

Not surprisingly, bowel symptoms reported at baseline were associated with having the same symptom at follow up. The short-term bowel symptoms were independently associated with some domains of long-term QoL.

The effect of a subsequent birth on bowel symptoms and QoL was an important area of interest. Two-thirds of the women had had a birth after that during which they sustained their OASIS and, of these, twice as many had a subsequent vaginal birth than a caesarean section.

The study showed an association between having long-term bowel symptoms and the various QoL domains and, not surprisingly, bowel function affected women's quality of life.

This study had an important advantage of being able to follow-up women in the longer-term with a mix of women having and not having a subsequent birth, but with the disadvantage of having different outcome assessment methods. The BASIQ cohort study, however, comprised a robust longitudinal cohort study design with the same measures of bowel function and QoL at baseline and follow-up, albeit with a shorter follow-up period. This will be described in the next chapter.

4 COHORT STUDY OF THE EFFECT OF BIRTH AND ITS MODE AFTER ANAL SPHINCTER INJURY ON BOWEL FUNCTION AND QUALITY OF LIFE (THE BASIQ STUDY)

4.1 Introduction

As demonstrated in the systematic review (see chapter two), there is a dearth of research regarding the long-term impact of a subsequent birth on bowel function and quality of life (QoL) for women who have previously sustained an OASIS. This means that the optimal method of birth for women with previous OASIS is unclear. Anal Incontinence (AI) is considered to have a negative impact on QoL (4). Anecdotal evidence linked to clinical impression suggests that bowel function can be classified as `abnormal' by a clinician but viewed as not bothersome by the patient. Indeed, quality improvement interventions and disease management programs often lack a framework that guides the selection of relevant, useful indicators. Without these the potential trade-off between quality of care and patient quality of life cannot be assessed (117). This concept supports the view that the aim should not just be to provide a better health service but to provide better health care for patients using the service.

For women with previous OASIS it is therefore vital that the long-term impact of having a subsequent birth is investigated in order to assist women and their clinicians when considering and deciding on the mode of this subsequent birth. In an age where all practice and recommendations should be evidence based it is important that the association between previous OASIS, further birth and its mode be

established. Most women with a previous obstetric anal sphincter injury have no bowel problems and when no defects in the anal sphincters are seen on ultrasound, the decision to pursue a vaginal birth is probably reasonable. Although this is becoming more accepted and wanted by women, information concerning the impact of this management on their bowel function in the longer term and the quality of life both prior to and following subsequent birth, either vaginal or caesarean section, is lacking. Evidence is required before the practice of promoting a particular mode of birth for women with previous OASIS that is considered optimal becomes routine.

4.2 Aim and Objectives

4.2.1 Aim

The aim of this study was to assess the impact of a subsequent birth and its mode on change in bowel function and QoL in pregnant women who had previously sustained OASIS.

4.2.2 Objectives

The objectives of this study were to:

a] explore any changes in women-reported bowel function and QoL at six months postpartum compared to 34 weeks' gestation.

b] evaluate the possible associations between mode of subsequent birth and any changes in reported bowel function and QoL at six months postpartum compared to 34 weeks' gestation.

c] compare anal sphincter integrity on endo-anal scan (EAUS) undertaken at both 34 weeks' gestation and six months postpartum.

d] investigate any association between mode of subsequent birth and bowel function at both 34 gestational weeks' and six months postpartum and anal sphincter muscle integrity.

4.3 Study Design

This was a prospective observational cohort study. A cohort study was chosen as it provides a longitudinal design that allows the study of a population from exposure (subsequent birth mode) to outcome (bowel function and QoL – see section 4.5). A cohort study design is also the best available scientific method for measuring the effects of a suspected risk factor. The main issues in the design of a cohort study are selection of the study group to allow generalisability of the study findings, measurement of exposure and outcome and methods of follow-up. Data comparable to the study outcome measurements are collected at the beginning of the study (baseline) and at a follow-up time point(s). In a cohort study, perhaps the biggest challenge is ensuring follow-up of a high proportion of the study population as failure to collect outcome data for too many participants will affect the validity of the study findings. Although cohort studies are prone to bias due to loss of follow-up and the generalisability of the findings is dependent on the representativeness of the cohort population, a cohort study design allows multiple outcomes to be measured for any one exposure, allows the measurement of incidence and prevalence and by undertaking a prospective cohort study the same data to assess the outcome can be

measured prior to and following the exposure. The study was designed, undertaken and reported using the STROBE (118), statement and checklist to ensure quality of the study findings and reporting (Appendix 4.1).

4.4 Population

The population was all pregnant women with a known history of having sustained a previous OASIS who had booked for a subsequent pregnancy at a single tertiary NHS Trust and referred to a specialist antenatal OASIS clinic.

4.4.1 Exclusion criteria:

There were only two exclusion criteria. Firstly, women under 16 years of age were excluded from the study. Secondly, because the bowel function and QoL outcome measures were collected using a self-reported and completed questionnaires that were validated for use in English, women who could not read and/or write in English had to be excluded.

4.5 Outcome measures

The main outcome measures were bowel function, QoL and changes to anal sphincter integrity. Bowel function and QoL were assessed by completion of the Manchester Health questionnaire (MHQ) (54). As detailed in section 1.3 the MHQ is a condition-specific validated health-related quality of life questionnaire for the assessment of women with anal incontinence. This was completed at six months following the subsequent birth and had also been completed at baseline at 34 weeks gestation. Anal sphincter integrity was assessed by EAUS (see section 1.2.2) that

were undertaken at six months following the subsequent birth and had also been undertaken at baseline at 34 weeks gestation.

4.6 Sample Size

Prior to the study women who had recently sustained any type of OASIS and were attending a dedicated postnatal OASIS clinic for multidisciplinary review were approached for their feedback about the necessity, acceptability and also possible interest in being recruited to this study. All of the 50 women (100%) approached gave positive feedback about the need and acceptability of this study and 70% (n=35) expressed a positive interest in being recruited to such a study if they were to have a future pregnancy. At the NHS Trust in which the study was undertaken, pregnant women who have previously sustained an OASIS have been referred to a specialist service and seen in a dedicated antenatal clinic since July 2007 (see section 1.4). At the time of study conception the number of such women averaged 125 women per year. Consequently, over the proposed two year study period, from the projected total of at least 250 women attending the specialised clinic a proposed sample size of 175 women (70%) was deemed achievable.

As demonstrated from the findings of the systematic review detailed in chapter three, there is little data on which to estimate the likely proportion of women with OASIS who have worsening in their bowel function if they go on to have a subsequent vaginal birth. If worsening occurred in 20% (35/175) of women in this study, the sample size of 175 women would allow a binomial exact 95% confidence interval spanning from 14% to 26% to be constructed giving reasonable precision. Even with

a very conservative estimate of worsening occurring in only 5% (9/175) of women in this study, a sample size of 175 women would allow a binomial exact 95% confidence interval spanning from 2% to 9% to be constructed to give reasonable precision.

4.7 Recruitment to the study

In the NHS Trust in which the study was undertaken, women with previous OASIS are managed in accordance with RCOG guidelines (40). Normal clinical practice is that women with a previous OASIS are identified by either the community or antenatal clinic midwife when they book their subsequent pregnancy and a note is made on their green handheld antenatal records. These women are then booked under the care of the Consultant Obstetrician who specialises in caring for women who have previously sustained an OASIS. All women with previous OASIS are given a 34 week antenatal clinic appointment with the Specialist Perineal Midwife in order for an EAUS to be undertaken and to discuss and plan the mode of birth for the current pregnancy. These women are also offered a routine six month postnatal EAUS clinic appointment to repeat the scans to assess anal sphincter muscle integrity following the subsequent birth. In addition to the data and investigations routinely undertaken, women recruited to the study were asked to complete a MHQ at both the 34 week antenatal clinic appointment and again at the six month postnatal clinic appointment. Apart from these data, the management of the pregnancy, labour and birth of all women recruited to the study was in line with our NHS Trust protocols. That is, by clinical indications, the wishes of the woman and department guidelines.

Midwives and obstetricians in the Trust were also approached for their opinion about the BASIQ study and its overall design. They were keen to support the study and its intention to establish more research evidence relating the long-term implications of OASIS as the study was designed to run seamlessly alongside NHS Trust routine guidelines.

Eligible women were approached to be recruited to the study at their 20 week antenatal clinic appointment by the Specialist Perineal Midwife and author of this thesis. Eligible women were provided with a study Patient Information Leaflet (PIL) alongside an introductory discussion about the aims, objectives and practical implications of being recruited to the study. Introducing the study at this antenatal clinic appointment gave a suitable amount of time (approximately 14 weeks) for the leaflet to be read and for women to consider if any further information or clarification was required prior to attending their routine 34 gestational weeks EAUS clinic appointment when the study would be re-discussed and consenting women recruited.

4.8 Data Collection

Data for the study was initially collected at the routine ante- and post-natal EAUS clinic appointments. However, after 12 months of the study in order to minimise attrition from women failing to attend the postnatal scheduled clinic appointment, ethical approval was gained from the NRES Committee West Midlands -South Birmingham Local Research Ethics Committee (13/WM/0367) for women to consent

to the MHQ being posted to them if they declined the six month postnatal EAUS appointment. A SAE was included for ease of return and encourage response.

All data required for the study was collected on study specific data forms as follows:

4.8.1 Antenatal study participant baseline characteristics

Participant baseline characteristics regarding date of birth, ethnicity, BMI at booking, gravida and parity at enrolment to the study was collected at recruitment (Appendix 4.2).

Details of previous labour(s) and birth(s) were also obtained, from their hospital records and captured on a study specific data form (Appendix 4.2), and included the following:

Date of birth, birthweight, mode of birth, whether labour was induced with reason, the classification of the previous OASIS they had sustained as per the RCOG guidelines (40) of 3A, 3B, 3C or 4 (if this was not known they were classified as ‘unspecified’), method of OASIS repair of ‘overlap’ or ‘end-to-end’ (if this was not known, repair was classified as ‘unspecified’), extent of any other previous perineal trauma and whether this was sutured, analgaesia in labour and maternal position at birth.

Occasionally some of this information was not available as the study participants’ previous birth(s) had not been at the NHS Trust in which the study was being undertaken.

4.8.2 Bowel function and QoL – at 34 gestational weeks and 6 months postnatal

Data for bowel function and QoL was collected from study participant self-completed MHQs at both 34 gestational weeks and at six months postnatal (Appendix 4.3). Section 1.3 provides more detailed information about how this information is recorded and scored. These questionnaires were anonymised by study participation reference number and, following completion, the study participant then sealed them in an envelope prior to being handed or posted to the Specialist Perineal Midwife.

4.8.3 Subsequent birth information

Data concerning planned mode of subsequent birth, reasons given by the women for choice of subsequent mode of birth, the actual mode of subsequent birth and any reason for a change in the planned mode of birth were obtained at both the antenatal and postnatal EAUS clinic appointments (Appendix 4.4).

Details of the actual subsequent birth were captured on a study specific data form (Appendix 4.4), and included the date of birth, birthweight and mode of birth,.

4.8.4 Endoanal Ultrasound scan findings – ante- and post- subsequent birth

EAUS results used for clinical diagnosis of defects in either the external or internal anal sphincters for both ante- and post- subsequent birth EAUS were recorded on a specific study data form (Appendix 4.5), and corresponding images also printed at the time of scan and filed in the study participants allocated data folder.

4.9 Data Analysis

4.9.1 Definition of characteristics

As detailed in section 1.3, bowel function and QoL of study participants were assessed using the MHQ (54) . This validated questionnaire captures the bowel function/symptoms of faecal urgency, difficulty wiping, poor control of flatus and faecal incontinence and consequent impact on QoL reflected in nine domains: General Health Perception (GHP), Incontinence Impact (II), Role Limitations (RL), Physical Limitations (PL), Social Limitations (SL), Personal Relationships (PR), Emotions (E), Sleep/Energy (SE) and Severity Measure (SM). Tables 4.1 and 4.2 are reference tables that define how bowel function and QoL scores, respectively, were classified for the data analyses undertaken. For bowel symptoms the characteristic 'any faecal leakage' was a composite of a combination of a positive recording of any frequency of passive leakage, leakage with coughing, leaking with walking, any loose or solid leakage or leaking with sexual intercourse. Consequently it was not possible to allocate this characteristic a score but to dichotomise this characteristic into 'absent' or 'present'.

Women in the study had mixed parity and the pregnancy during the study period was not always that immediately subsequent to the birth during which OASIS was sustained. Table 4.3 lists the definitions for the births experienced for the women in the study.

Table 4.1 Characteristic definition of bowel symptoms for data analysis

Bowel function/symptoms	
Characteristic definition/classification	Description
'Never' 'Occasionally' 'Sometimes' 'Most of the time' 'All of the time'	Frequency of bowel function/symptom as recorded in the MHQ.
'Worsened' - when the frequency of the symptom at postnatal MHQ completion was recorded as having occurred more often than that recorded in the antenatal MHQ. 'No change' - when the frequency of the bowel symptom at postnatal MHQ completion was the same as that recorded in the antenatal MHQ. 'Improved' - when the frequency of the bowel symptom at postnatal MHQ completion was less than that recorded in the antenatal MHQ.	Any change in the frequency of the bowel symptom recorded in the postnatal MHQ compared to that recorded in the antenatal MHQ.
'Absent' - when the frequency of the symptom was recorded as 'Never' on the MHQ. 'Present' when the frequency of the symptom was recorded as 'Occasionally' or 'Sometimes' or 'Most of the time' or 'All of the time' on the MHQ.	The presence of a bowel symptom
'Any faecal leakage '	The presence of any type of faecal leakage with a recording of any of the following symptoms at any frequency - passive leakage, leakage with coughing, leaking with walking, any loose or solid leakage or leaking with sexual intercourse.

Table 4.2 Characteristic classification of QoL scoring for data analysis

QoL	
Characteristic classification	Description
0 1-25 26-50 51-75 76-100	QoL domain total score calculated from a scoring system whereby a lower score equates to less impact on QoL (see section 1.3).
'Worsened' - when the QoL domain score at postnatal MHQ completion was higher than the corresponding domain score in the antenatal MHQ. 'No change' - when the QoL domain score at postnatal MHQ completion was the same as the corresponding domain score in the antenatal MHQ. 'Improved' - when the QoL domain score at postnatal MHQ completion was lower than the corresponding domain score in the antenatal MHQ.	Any change in the QoL domain score in the postnatal MHQ compared to the corresponding QoL domain score in the antenatal MHQ.
'No effect' - a score of 0 was deemed indicative of no effect on QoL as this score is calculated from the answers of 'never' 'Negative effect' - a score of ≥ 1 was deemed indicative of a negative effect on QoL as this score is calculated from the answers of 'rarely', 'sometimes', 'often' and 'always'	The effect on QoL

Table 4.3 Definitions of birth characteristics for data analysis

Definitions of births	
Characteristic definition	Description
'OASIS birth'	The birth during which the OASIS was sustained.
'Study birth'	The subsequent birth that was experienced during the study.
'Vaginal interval birth'	A vaginal birth that has occurred following the 'OASIS birth' and prior to the' Study birth'

4.9.2 Statistical methods

Data were analysed using STATA® (107) and SPSS® (108). Differences in baseline characteristics were analysed using two-sample t-test for continuous characteristics, Mann-Whitney *U* test for skewed data, Chi-square test for categorical characteristics when the numbers in each cell were greater than or equal to five and a Fischer's exact test for categorical characteristics when the numbers in the cell were less than or equal to five. A $p<0.05$ was considered statistically significant.

A multivariate logistic regression model providing odds ratios (OR) and 95% confidence intervals (95% CI), was used to evaluate interaction between possible independent characteristics (OASIS birth mode, mode of study birth, vaginal interval birth, bowel symptoms at initial hospital review, maternal age at OASIS, years between OASIS and questionnaire completion, total parity, OASIS classification, repair method and birthweight) and outcome characteristics (bowel function and MHQ QoL domains).

4.10 Ethical approval

Ethical approval was gained from NRES Committee West Midlands -South Birmingham Local Research Ethics Committee (13/WM/0367). Study participants were asked to sign a study consent form (Appendix 4.6) that gave permission to access relevant sections of hospital notes for additional information and also gave the option for agreement for being contacted in the future for further research into this area.

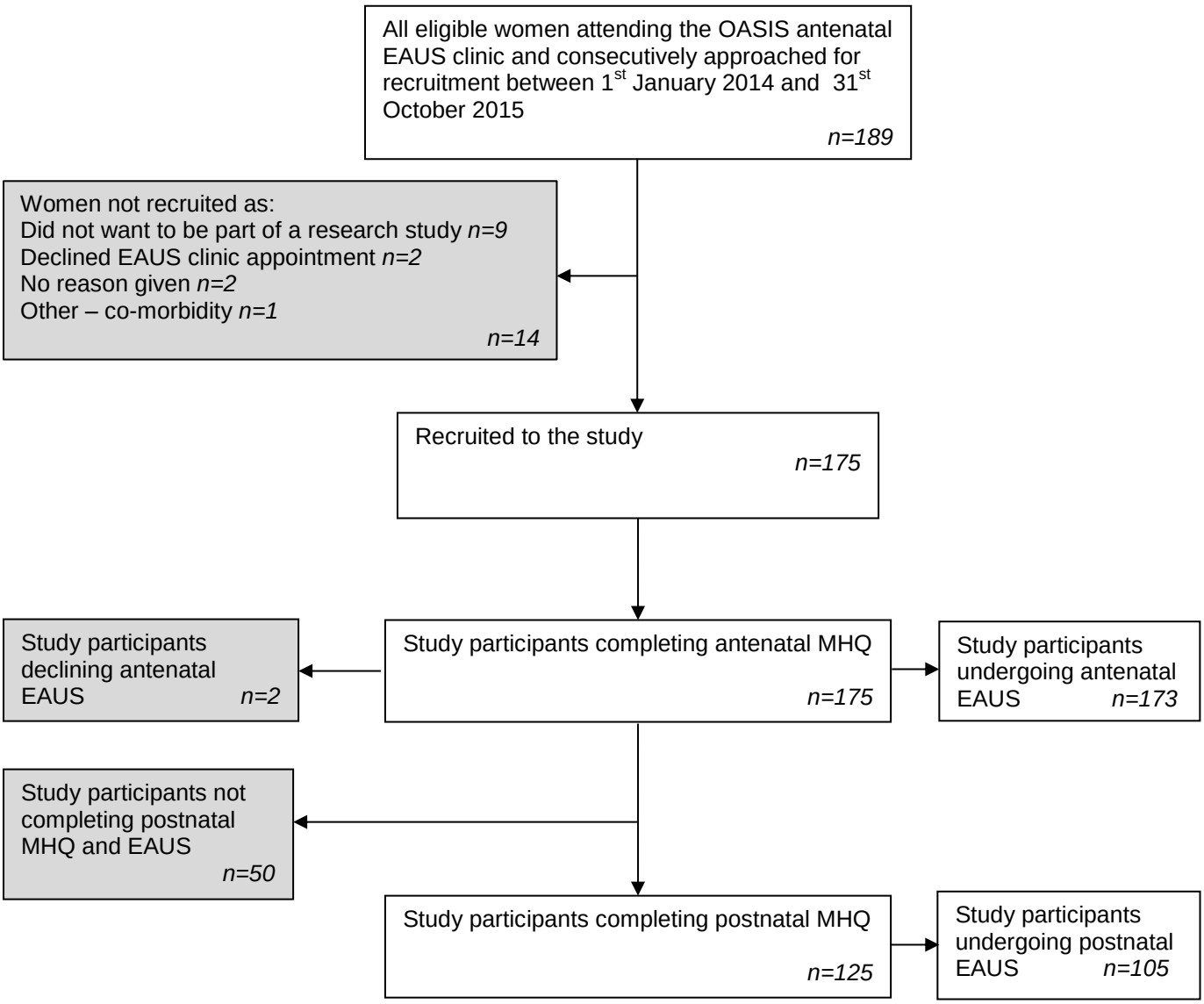
4.11 Results

4.11.1 Cohort sample - recruitment and follow-up rates

All 189 eligible women with previous OASIS and attending the routine antenatal clinic for EAUS and to discuss mode of birth for their current pregnancy were approached for recruitment between 1st January 2014 and 31st October 2015. During this 22 month period the required sample size of 175 women were recruited to the study, a recruitment rate of 92.6%. Only 14/189 eligible women were not recruited; 2 declined their EAUS clinic appointment as they had already decided on having an elective caesarean section for their subsequent mode of birth, 9 women did not wish to take part in research, 2 women declined with no reason given and 1 woman declined as she felt her co-morbidity of Crohn's disease would bias her MHQ answers. The study recruitment flowchart is presented in figure 4.1. Of the 175 study participants who completed the antenatal MHQ, 98.9% (173/175) of these women also had an antenatal EAUS. The mean gestation of the women at recruitmen to the study was 32^{+4} gestational weeks.

All study participants were offered a routine six month postnatal EAUS clinic appointment and if they declined were posted the MHQ. Of these 71.4% (125/175) women returned their postnatal MHQ. Of these 125 women, 105 women (84%) attended the postnatal clinic appointment and had an EAUS and 20 women (16%) declined this appointment and completed the MHQ by post. The mean time period between the study birth and the completion of the postnatal MHQ was 6.8 months [± 2.17 months].

Figure 4.1 Recruitment and follow-up rates



4.11.2 Baseline characteristics of women recruited to the study

Table 4.4 shows the baseline maternal, OASIS, labour and neonatal characteristics of all of the women recruited to the study. Just under half of the women were of white ethnicity (48.6%) and the majority of the women had a parity of one (72.0%). In the group of women where the type of OASIS sustained was documented (n=132, 75.4%), the most common reported classification was a 3B injury (33.1%). The presence of either an area of excessive scarring or an anal sphincter defect was found on 24.3% (42/175) of the women during their antenatal EAUS. Regarding the mode of birth during which the OASIS was sustained, the majority of the women had undergone a spontaneous vaginal birth (60.0%). Seventy women (40%), sustained their OASIS during an operative vaginal birth, with 65.7% of these (46/70) sustained during low/unspecified forceps assisted birth. Fifty-eight women (33.1%) had their labour induced and forty-one women (23.4%) had epidural analgaesia during the OASIS birth (23.4%). Gestational weeks for the birth during which OASIS occurred was 39 completed gestational weeks with a mean birthweight of 3448gms.

Of the 175 women who were recruited to the study, the 50 women who did not complete the postnatal MHQ were compared to those who did to determine if there were any differences. There was no difference in the baseline maternal characteristics of age at OASIS, ethnicity, BMI and parity at recruitment to the study between the women who completed the postnatal MHQ and those that did not. Likewise OASIS characteristics of trauma classification and whether an anal sphincter defect was present were also comparable between the two groups. However there was a significant difference in method of OASIS repair between the

two groups with more women who completed the postnatal questionnaire having either an end-to-end or overlap repair and more women who did not complete the postnatal questionnaire having an unspecified method of repair. The labour characteristics for the birth during which OASIS was sustained for mode of OASIS birth, whether the OASIS birth was induced or involved epidural anaesthesia and maternal position at the OASIS birth were also comparable between the two groups. Neonatal characteristics of the OASIS birth of gestational age and head circumference were comparable between the two groups, with the only significant difference being birthweight, with women who completed the postnatal MHQ having a heavier baby than those women who did not.

Table 4.4 Baseline characteristics of all participants with comparison between women who completed the postnatal MHQ and those who did not

Characteristics, n (%)	All women N=175	Postnatal MHQ N=125	No postnatal MHQ N=50	*p*-value
Maternal characteristics				
Age at OASIS (years), mean [SD]	27.8 [4.6]	28.1 [4.4]	27.2 [4.9]	0.294
Ethnicity				
White	85 (48.6)	64 (51.2)	21 (42.0)	
Mixed/Multiple	2 (1.1)	0	2 (4.0)	
Asian/Asian British	60 (34.3)	40 (32.0)	20 (40.0)	
Black/African/Caribbean/Black British	22 (12.6)	16 (12.8)	6 (12.0)	
Other/Not Known	6 (3.4)	5 (4.0)	1 (2.0)	
BMI, mean [SD]	26.5 [5.7]	26.1 [5.2]	27.6 [6.8]	0.159
Parity at recruitment				0.497
1	126 (72.0)	87 (69.6)	39 (78.0)	
2	40 (22.9)	30 (24.0)	10 (20.0)	
≥3	9 (5.1)	8 (6.4)	1 (2.0)	
Gestation at recruitment, (weeks), median [IQR][¥]	32 [31,33]	32 [31,33]	32 [31,33]	0.717
OASIS characteristics				
OASIS classification				0.334
3A	50 (28.6)	37 (29.6)	13 (26.0)	
3B	58 (33.1)	43 (34.4)	15 (30.0)	
3C/4	24 (13.71)	19 (15.2)	5 (10.0)	
Unspecified	43 (24.6)	26 (20.8)	17 (34.0)	
Method of repair				*0.045*
End-to-end	72 (41.1)	55 (44.0)	17 (34.0)	
Overlap	53 (30.3)	41 (32.8)	12 (24.0)	
Unspecified	50 (28.6)	29 (23.2)	21 (42.0)	
Anal sphincter defect on antenatal EAUS [↗]				0.054
Present	42 (24.3)	35 (28.2)	7 (14.3)	
Absent	131 (75.7)	89 (71.8)	42 (85.7)	
Labour characteristics for OASIS birth				
Mode of OASIS birth				0.058
SVD	105 (60.0)	75 (60.0)	30 (60.0)	
Kiwi/ventouse	17 (9.7)	16 (12.8)	1 (2.0)	
Low/unspecified forceps	46 (26.3)	28 (22.4)	18 (36.0)	
Rotational forceps	7 (4.0)	6 (4.8)	1 (2.0)	
Induction of labour	58 (33.1)	43 (34.4)	15 (30.0)	0.576
Epidural	41 (23.4)	31 (24.8)	10 (20.0)	0.498
Maternal position at birth				0.191
Lithotomy	74 (42.3)	52 (41.6)	22 (44.0)	
Supported sitting	72 (41.1)	47 (37.6)	25 (50.0)	
All fours	4 (2.3)	3 (2.4)	1 (2.0)	
Standing	2 (1.1)	2 (1.6)	0	
Lateral	1 (0.6)	1 (0.8)	0	
Kneeling	10 (5.7)	9 (7.2)	1 (2.0)	
McRoberts	5 (2.9)	5 (4.0)	0	
Squatting	1 (0.6)	0	1 (2.0)	
Not known	6 (3.4)	6 (4.8)	0	

Neonatal characteristics for OASIS birth				
Gestational age, (weeks), median [IQR]¥	39 [39,40]	40 [39,40]	40 [38,40]	0.197
Birth weight, (kg), mean [SD]	3.448 [0.595]	3.538 [0.537]	3.224 [0.676]	*0.001*
Head circumference (cms), mean [SD]	34.1 [3.4]	34.2 [3.8]	33.9 [1.7]	0.709

IQR: interquartile range; SD: standard deviation.
The *t* test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data) ¥, and χ^2 test or Fischer exact test for categorical characteristics with missing excluded, as appropriate due to small numbers≠
↗ N=173, two women declined antenatal EAUS

Table 4.5 shows the baseline bowel function at antenatal MHQ completion for the 175 women recruited to the study. There were 74.9% (131/175) of the women who reported having experienced an episode of bowel urgency and 48.0% (84/175) of the women who reported experiencing poor control of flatus at any time. Difficulty in wiping clean following a bowel motion was experienced by 37.1% (65/175) of the women. With regard to faecal leakage, 25.7% (45/175) of the women reported having had any episode of faecal leakage. Of the various times when faecal leakage occurred, the most common was with coughing/sneezing experienced by 14.3% (25/175) of women. Faecal leakage with walking was experienced by 4.6% (8/175) of the women and 1.7% (3/175) of the women had experienced faecal leakage during sexual intercourse. Passive faecal leakage (ie, not associated with any physical activity) was experienced by 4.6% (8/175) of the women. All reported bowel leakage was of loose stools and no woman reported solid stool incontinence.

A comparison of the baseline bowel function at antenatal MHQ completion between study participants who completed the postnatal MHQ (n=125) and those women who did not (n=50) was undertaken to consider whether respondents were representative and is shown in table 4.5. Bowel function at antenatal questionnaire completion between the two groups was comparable for faecal urgency, difficulty wiping clean, leakage – passive only, leakage with coughing/sneezing, leakage with walking, leakage during SI, loose leakage, solid leakage and any bowel leakage. The only significant difference was with control of flatus with more women who completed the postnatal MHQ having poor control of flatus at the time of antenatal questionnaire completion.

Table 4.5 Baseline characteristics of all participants bowel function with comparison between women who completed postnatal MHQ those who did not

Characteristics, n (%)	All recruited women N=175	Respondents to postnatal MHQ N=125	No postnatal MHQ N=50	*p*-value
Bowel function at antenatal questionnaire completion				
Bowel urgency				0.428
Never	44 (25.1)	28 (22.4)	16 (32.0)	
Occasionally	69 (39.4)	50 (40.0)	19 (38.0)	
Sometimes	50 (28.6)	39 (31.2)	11 (22.0)	
Most of the time	10 (5.7)	6 (4.8)	4 (8.0)	
All of the time	2 (1.1)	2 (1.6)	0	
Difficulty wiping clean				0.219
Never	110 (62.9)	73 (58.4)	37 (74.0)	
Occasionally	35 (20.0)	30 (24.0)	5 (10.0)	
Sometimes	15 (8.6)	11 (8.8)	4 (8.0)	
Most of the time	13 (7.4)	9 (7.2)	4 (8.0)	
All of the time	2 (1.1)	2 (1.6)	0	
Poor control of flatus				*0.001*
Never	91 (52.0)	53 (42.4)	38 (76.0)	
Occasionally	45 (25.7)	38 (30.4)	7 (14.0)	
Sometimes	20 (11.4)	18 (14.4)	2 (4.0)	
Most of the time	15 (8.6)	14 (11.2)	1 (2.0)	
All of the time	4 (2.3)	2 (1.6)	2 (4.0)	
Faecal leakage- passive only				0.353
Never	167 (95.4)	118 (94.4)	49 (98.0)	
Occasionally	5 (2.9)	5 (4.0)	0	
Sometimes	3 (1.7)	2 (1.6)	1 (2.0)	
Most of the time	0	0	0	
All of the time	0	0	0	
Faecal leakage with coughing/sneezing				0.501
Never	150 (85.7)	107 (85.6)	43 (86.0)	
Occasionally	17 (9.7)	13 (10.4)	4 (8.0)	
Sometimes	6 (3.4)	3 (2.4)	3 (6.0)	
Most of the time	0	2 (1.6)	0	
All of the time	0	0	0	
Faecal leakage with walking				0.433
Never	167 (95.4)	118 (94.4)	49 (98.0)	
Occasionally	4 (2.3)	4 (3.2)	0	
Sometimes	4 (2.3)	3 (2.4)	1 (2.0)	
Most of the time	0	0	0	
All of the time	0	0	0	

Faecal leakage during SI				0.225
Never	172 (95.4)	124 (99.2)	48 (96.0)	
Occasionally	4 (2.3)	1 (0.8)	1 (2.0)	
Sometimes	4 (2.3)	0	1 (2.0)	
Most of the time	0	0	0	
All of the time	0	0	0	
Faecal leakage – loose stool				0.442
Never	141 (98.3)	99 (79.2)	42 (84.0)	
Occasionally	2 (1.1)	15 (12.0)	4 (8.0)	
Sometimes	1 (0.6)	9 (7.2)	2 (4.0)	
Most of the time	0	1 (0.8)	2 (4.0)	
All of the time	0	1 (0.8)	0	
Faecal leakage – solid stool				
Never	175 (100.0)	125 (100.0)	50 (100.0)	-----
Any faecal leakage				0.956
Yes	130 (74.3)	32 (25.6)	13 (26.0)	
No	45 (25.7)	93 (74.4)	37 (74.0)	

IQR: interquartile range; SD: standard deviation.
The *t* test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data) [¥], and χ^2 test for categorical characteristics with missing excluded as appropriate due to small numbers [≠]

The antenatal QoL domain scores for all women recruited to the study are detailed in table 4.6. There were 58.9% (103/175) of the women who reported a negative impact on 'General Health Perception' and 42.3% (74/175) of the women who reported a negative 'Incontinence Impact'. For the QoL domain of 'Role Limitations', 73.1% (128/175) women reported a negative impact. There were 17.1% (30/175) of the women who reported a negative impact on the domain of 'Physical Limitations' and 12.6% (30/175) of the women reported a negative impact on 'Social Limitations'. A negative impact on 'Personal Relationships' was reported by 12.6% (17/175) of the women. There were 28.6% (50/175) of the women who reported a negative impact on the domain of 'Emotions' and 14.3% (35/175) of the women who reported a negative impact on 'Sleep/Energy'. For the QoL domain of 'Severity Measure', 32.0% (56/175) women reported a negative impact prior to the study birth.

Table 4.6 also shows the comparison of the baseline QoL domain scores at antenatal MHQ completion between women recruited to the study who completed postnatal follow-up MHQ (n=125) and those women who did not (n=50). All QoL domain scores were comparable between the two groups except the QoL domain of 'Emotion' with more women who completed the postnatal MHQ having a score indicating bowel symptoms and this resulted in a negative impact in this QoL domain.

Table 4.6 Baseline characteristics of all participants antenatal QoL with comparison of women who completed the postnatal MHQ and those who did not

Characteristics, n (%)	All recruited women N=175	Postnatal MHQ N=125	No postnatal MHQ N=50	*p*-value
QoL domain scores at antenatal questionnaire completion				
General Health Perception (GHP)				0.628
0	72 (41.1)	51 (40.8)	21 (42.0)	
1-25	81 (46.3)	56 (44.8)	25 (50.0)	
26-50	20 (11.4)	16 (12.8)	4 (8.0)	
51-75	2 (1.1)	2 (1.6)	0	
76-100	0	0	0	
Incontinence Impact (II)				0.076
0	101 (57.7)	67 (53.6)	34 (68.0)	
1-25	49 (28.0)	35 (28.0)	14 (28.0)	
26-50	15 (8.6)	14 (11.2)	1 (2.0)	
51-75	8 (4.6)	8 (6.4)	0	
76-100	2 (1.1)	1 (0.8)	1 (2.0)	
Role Limitations (RL)				0.808
0	47 (26.9)	32 (25.6)	15 (30.0)	
1-25	117 (66.9)	85 (68.0)	32 (64.0)	
26-50	9 (5.1)	7 (5.6)	2 (4.0)	
51-75	2 (1.1)	1 (0.8)	1 (2.0)	
76-100	0	0	0	
Physical Limitations (PL)				0.090
0	145 (82.9)	99 (79.2)	46 (92.0)	
1-25	16 (9.1)	14 (11.2)	2 (4.0)	
26-50	12 (6.9)	11 (8.8)	1 (2.0)	
51-75	1 (0.6)	0	1 (2.0)	
76-100	1 (0.6)	1 (0.8)	0	
Social Limitations (SL)				0.226
0	153 (87.4)	106 (84.8)	47 (94.0)	
1-25	17 (9.7)	15 (12.0)	2 (4.0)	
26-50	3 (1.7)	3 (2.4)	0	
51-75	0	1 (0.8)	1 (2.0)	
76-100	2 (1.1)	0	0	
Personal Relationships (PR)				0.053
0	158 (87.4)	109 (87.2)	49 (98.0)	
1-25	17 (9.7)	14 (11.2)	0	
26-50	3 (1.7)	1 (0.8)	0	
51-75	0	0	1 (2.0)	
76-100	2 (1.1)	1 (0.8)	0	
Emotions (E)				*0.012*
0	125 (71.4)	80 (64.0)	45 (90.0)	
1-25	28 (16.0)	25 (20.0)	3 (6.0)	
26-50	15 (8.6)	14 (11.2)	1 (2.0)	
51-75	4 (2.3)	4 (3.2)	0	

76-100	3 (1.7)	2 (1.6)	1 (2.0)	
Sleep/Energy (SE)				0.443
0	150 (85.7)	105 (84.0)	45 (90.0)	
1-25	16 (9.1)	12 (9.6)	4 (8.0)	
26-50	6 (3.4)	6 (4.8)	0	
51-75	3 (1.7)	2 (1.6)	1 (2.0)	
76-100	0	0	0	
Severity Measure (SM)				0.155
0	119 (68.0)	79 (63.2)	40 (80.0)	
1-25	40 (22.9)	32 (25.6)	8 (16.0)	
26-50	10 (5.7)	9 (7.2)	1 (2.0)	
51-75	4 (2.3)	4 (3.2)	0	
76-100	2 (1.1)	1 (0.8)	1 (2.0)	

IQR: interquartile range; SD: standard deviation.
The *t* test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data) [¥], and χ^2 test for categorical characteristics with missing excluded as appropriate due to small numbers [≠]

4.11.3 Baseline characteristics of women who completed postnatal MHQ

From the 125 women who responded to follow-up, 105 women completed the postnatal MHQ during attendance at their routine postnatal follow-up clinic appointment and 20 women by post. These two groups were compared to determine if there was any difference in women who chose not to attend the clinic appointment (table 4.7). There were no differences in any of the baseline maternal, labour or neonatal characteristics between the groups except that there was a significant difference in the presence of anal sphincter defects with slightly more women with a known anal sphincter defect attending for the postnatal clinic appointment. Bowel function (table 4.8) and QoL (table 4.9) were also similar between those who attended their appointment and those who completed the MHQ by post.

Table 4.7 Baseline characteristics of participants –postnatal clinic follow-up and postnatal postal follow-up

Characteristics, n (%)	Postnatal clinic follow-up N=105	Postnatal postal follow-up N=20	*p*-value
Maternal characteristics			
Age at OASIS (years), mean [SD]	27.9 [4.4]	28.7 [4.5]	0.494
Ethnicity			0.473
White	52 (49.5)	12 (60.0)	
Mixed/Multiple	0	10 (0.0)	
Asian/Asian British	33 (31.4)	7 (35.0)	
Black/African/Caribbean/Black British	15 (14.3)	1 (5.0)	
Other/Not Known	5 (4.8)	0	
BMI, mean [SD]	26.2 [5.3]	26.0 [4.5]	0.913
Parity at recruitment			0.472
1	75 (71.4)	12 (60.0)	
2	23 (21.9)	7(35.0)	
≥3	7 (6.7)	1 (5.0)	
OASIS characteristics			
OASIS classification			0.918
3A	31 (29.5)	6 (30.0)	
3B	37 (35.2)	6 (30.0)	
3C/4	15 (14.3)	4 (20.0)	
Unspecified	22 (21.0)	4 (20.0)	
Method of repair			0.930
End-to-end	46 (43.8)	9 (45.0)	
Overlap	34 (32.4)	7 (35.0)	
Unspecified	25 (23.8)	4 (20.0)	
Anal sphincter defect on antenatal EAUS			*0.040*
Present	30 (28.6)	5 (26.3)	
Absent	75 (71.4)	14 (73.7)	
Labour characteristics for OASIS birth			
Mode of birth			0.452
SVD	62 (59.0)	13 (65.0)	
Kiwi/ventouse	15 (14.3)	1 (5.0)	
Low/unspecified forceps	24 (22.9)	4 (20.0)	
Rotational forceps	4 (3.8)	2 (10.0)	
Induction of labour	37 (35.2)	6 (30.0)	0.651
Epidural	25 (23.8)	6 (30.0)	0.557
Maternal position at birth			0.078
Lithotomy	45 (42.9)	7 (35.0)	
Supported sitting	39 (37.1)	8 (40.0)	
All fours	1 (1.0)	2 (10.0)	
Standing	2 (1.9)	0	
Lateral	0	1 (5.0)	
Kneeling	8 (7.6)	1 (5.0)	
McRoberts	5 (4.8)	0	
Squatting	0	0	
Not known	5 (4.8)	1 (5.0)	

Neonatal characteristics for OASIS birth			
Gestational age, (weeks), median [IQR]¥	40 [39, 40]	40 [38, 40]	0.645
Birth weight, (kg), mean [SD]	3.546 [0.529]	3.490 [0.587]	0.664
Head circumference (cms), mean [SD]	34.0 [4.1]	35.0 [1.6]	0.324

IQR: interquartile range; SD: standard deviation.
The *t* test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data)¥, and χ^2 test for categorical characteristics with missing excluded as appropriate due to small numbers≠

Table 4.8 Baseline characteristics of participants bowel function –postnatal clinic follow-up and postnatal postal follow-up

Characteristics, n (%)	Postnatal clinic follow-up N=105	Postnatal postal follow-up N=20	*p*-value
Bowel function at antenatal questionnaire completion			
Bowel urgency			0.292
Never	25 (23.8)	3 (15.0)	
Occasionally	43 (41.0)	7 (35.0)	
Sometimes	29 (27.6)	10 (50.0)	
Most of the time	6 (5.7)	0	
All of the time	2 (1.9)	0	
Difficulty wiping clean			0.891
Never	60 (57.1)	13 (65.0)	
Occasionally	25 (23.8)	5 (25.0)	
Sometimes	10 (9.5)	1 (5.0)	
Most of the time	8 (7.6)	1 (5.0)	
All of the time	2 (1.9)	0	
Poor control of flatus			0.421
Never	43 (41.0)	10 (50.0)	
Occasionally	32 (30.5)	6 (30.0)	
Sometimes	14 (13.3)	4 (20.0)	
Most of the time	14 (13.3)	0	
All of the time	2 (1.9)	0	
Faecal leakage- passive only			0.494
Never	98 (93.3)	20 (100.0)	
Occasionally	5 (4.8)	0	
Sometimes	2 (1.9)	0	
Most of the time	0	0	
All of the time	0	0	
Faecal leakage with coughing/sneezing			0.369
Never	91 (86.7)	16 (80.0)	
Occasionally	9 (8.6)	4 (20.0)	
Sometimes	3 (2.9)	0	
Most of the time	2 (1.9)	0	
All of the time	0	0	
Faecal leakage with walking			0.494
Never	98 (93.3)	20 (100.0)	
Occasionally	4 (3.8)	0	
Sometimes	3 (2.9)	0	
Most of the time	0	0	
All of the time	0	0	
Faecal leakage during SI			0.661
Never	104 (99.0)	20 (100.0)	
Occasionally	1 (1.0)	0	
Sometimes	0	0	
Most of the time	0	0	
All of the time	0	0	

Faecal leakage – loose stool			0.640
Never	84 (80.0)	15 (75.0)	
Occasionally	13 (12.4)	2 (10.0)	
Sometimes	6 (5.7)	3 (15.0)	
Most of the time	1 (1.0)	0	
All of the time	1 (1.0)	0	
Faecal leakage – solid stool			----
Never	105 (100.0)	20 (100.0)	
Any faecal leakage			0.623
No	79 (75.2)	14 (70.0)	
Yes	26 (24.8)	6 (30.0)	

IQR: interquartile range; SD: standard deviation.
The *t* test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data) [¥], and χ^2 test for categorical characteristics with missing excluded as appropriate due to small numbers[≠]

Table 4.9 Baseline characteristics of participants QoL –postnatal clinic follow-up and postnatal postal follow-up

Characteristics, n (%)	Postnatal clinic follow-up N=105	Postnatal postal follow-up N=20	*p*-value
QoL domain scores at antenatal questionnaire completion			
General Health Perception (GHP)			0.600
0	43 (41.0)	8 (40.0)	
1-25	47 (44.8)	9 (45.0)	
26-50	14 (13.3)	2 (10.0)	
51-75	1 (1.0)	1 (5.0)	
76-100	0	0	
Incontinence Impact (II)			0.467
0	59 (56.2)	8 (40.0)	
1-25	26 (24.8)	9 (45.0)	
26-50	12 (11.4)	2 (10.0)	
51-75	7 (6.7)	1 (5.0)	
76-100	1 (1.0)	0	
Role Limitations (RL)			0.741
0	25 (23.8)	7 (35.0)	
1-25	73 (69.5)	12 (60.0)	
26-50	6 (5.7)	1 (5.0)	
51-75	1 (1.0)	0	
76-100	0	0	
Physical Limitations (PL)			0.967
0	83 (79.0)	16 (80.0)	
1-25	12 (11.4)	2 (10.0)	
26-50	9 (8.6)	2 (10.0)	
51-75	1 (1.0)	0	
76-100	0	0	
Social Limitations (SL)			0.553
0	90 (85.7)	16 (80.0)	
1-25	11 (10.5)	4 (20.0)	
26-50	3 (2.9)	0	
51-75	1 (1.0)	0	
76-100	0	0	
Personal Relationships (PR)			0.538
0	93 (88.6)	16 (80.0)	
1-25	10 (9.5)	4 (20.0)	
26-50	1 (1.0)	0	
51-75	1 (1.0)	0	
76-100	0	0	
Emotions (E)			0.783
0	67 (63.8)	13 (65.0)	
1-25	20 (19.0)	5 (25.0)	
26-50	13 (12.4)	1 (5.0)	
51-75	3 (2.9)	1 (5.0)	
76-100	3 (1.9)	0	
Sleep/Energy (SE)			0.304

0	89 (84.8)	16 (80.0)	
1-25	11 (10.5)	1 (5.0)	
26-50	4 (3.8)	2 (10.0)	
51-75	1 (1.0)	1 (5.0)	
76-100	0	0	
Severity Measure (SM)			0.478
0	66 (62.9)	13 (65.0)	
1-25	25 (23.8)	7 (35.0)	
26-50	9 (8.6)	0	
51-75	4 (3.8)	0	
76-100	1 (1.0)	0	

IQR: interquartile range; SD: standard deviation.
The *t* test was conducted for continuous parameters (with Mann-Whitney *U* test for skewed data) [¥], and χ^2 test for categorical characteristics with missing excluded as appropriate due to small numbers[≠]

4.11.4 Mode of study birth: choice and actual

Of the 175 women recruited to the study, 60.6% (106/175) chose to pursue a vaginal birth and 36.6% (64/175) of women opted for an elective caesarean section. The remaining 2.8% (5/175) of women made a birth plan that encompassed either a vaginal birth or caesarean section depending on ante-/intra-partum events; one woman opted to pursue a vaginal birth unless intrapartum augmentation of labour was indicated and then she would undergo an emergency caesarean section; four women opted for an elective caesarean booked for the day they would be induced for prolonged pregnancy (40 gestational weeks and 10 days) unless they went into spontaneous labour prior this whereby they would pursue a vaginal birth.

Table 4.10 shows the chosen mode of birth for all 175 women recruited to the study in relation to their baseline antenatal EAUS findings. Despite extensive scarring or an anal sphincter defect being diagnosed at the antenatal EAUS, 2 women (1.9%) chose to pursue a vaginal birth, whereas the remaining 104 women (98.1%) who decided to pursue a vaginal birth had no anal sphincter defect visible. From the 64 women who chose an elective caesarean section for the birth, 62.5% (40/64) had a known anal sphincter defect and two women (3.1%) chose an elective caesarean section without having an EAUS to determine anal sphincter integrity. There were no antenatal anal sphincter defects visible for any of the five women who decided to pursue a birth mode that may have involved either vaginal birth or caesarean section.

Table 4.11 details the reasons given by the 175 women recruited to the study as being the main characteristic(s) in their decision to pursue a specified mode of birth. The associated risks (maternal and fetal) from an elective caesarean section were stated by 91.5% (97/106) of women choosing to pursue a vaginal birth and 20% (1/5) of women who whose mode of study birth would encompass either a vaginal birth or caesarean section as being an important reason for their decision. For women choosing an elective caesarean section, the most frequently cited reason for 81.5% (53/64) of women, was the trauma that they had experienced (both physical and psychological) from the labour and birth in which the OASIS was sustained. This was also a reason given by 80.0% (4/5) of the women choosing to pursue either a vaginal birth or caesarean section. Fear of a repeat OASIS from a subsequent vaginal birth was given by 50.0% (32/64) of women as a reason for opting for an elective caesarean section, and by 100% (5/5) of the women opting to pursue either a vaginal birth or caesarean section. The fear of worsening of existing bowel symptoms and anal sphincter defects seen on EAUS (in line with RCOG guidelines for discussion and consideration of elective caesarean when present), were the main reason why 31.2% (20/64) and 62.5% (40/64) of women gave, respectively, for choosing an elective caesarean section.

Table 4.10 A comparison of chosen mode of study birth and anal sphincter integrity

	Planned mode of study birth			Total
Anal sphincter findings on antenatal EAUS, n (%)	Vaginal birth	Elective caesarean section	Either	
Extensive scarring or defect present (IAS±EAS)	2 (1.9)	40 (62.5)	0	42
No sphincter abnormality	104 (98.1)	22 (34.4)	5 (100)	131
EAUS declined	0	2 (3.1)	0	2
Total	106 (100)	64 (100)	5 (100)	175 (100)

Table 4.11 Reasons women gave for pursuing planned mode of study birth

	Planned mode of study birth		
Reason for mode of birth choice, n (%)	Vaginal birth (n=106)	Elective caesarean section (n=64)	Either (n=5)
Fear of worsening of existing bowel symptoms	0	20 (31.2)	0
Fear of repeat OASIS	0	32 (50.0)	5 (100.0)
Previous traumatic labour and birth	0	53 (81.5)	4 (80.0)
Anal sphincter defects seen on EAUS	0	40 (62.5)	0
Risks associated with caesarean section	97 (91.5)	0	1 (20.0)

A comparison of the actual mode of study birth compared to the planned mode is shown in table 4.12. The five women who chose to pursue a birth mode that may have involved either a vaginal or caesarean birth depending on ante-/intra-partum events, were removed from this comparison analysis. From the 170 women with a clear mode of birth choice 94.1% (160/170) ended up having their planned mode of birth: 97.1% (99/102) achieved the vaginal birth they planned and 90.0% (61/68) underwent a caesarean as planned. Of the 10 women who underwent a change in planned mode of birth, four women subsequently changed their mind with three of them opting for an elective caesarean section after originally deciding to pursue a vaginal birth and one woman choosing vaginal birth after originally booking for elective caesarean section. Two women who were originally booked for elective caesarean section were admitted in established labour and progressed to a vaginal birth too quickly for an emergency caesarean section to be performed and four women had clinical indications necessitating emergency caesarean section rather than a vaginal birth as planned.

Table 4.12 Women who did/ did not get planned mode of study birth

	Actual mode of study birth		
N=170[¥]	Vaginal birth	Caesarean section	Total
Planned mode of study birth, n (%)			
Vaginal birth	99 (97.1)	7 (10.0)	106 (62.4)
Caesarean section	3 (2.9)	61 (90.0)	64 (37.6)
Total	102 (100)	68 (100)	170 (100)

[¥] excludes five women who were pursuing a mode if birth that may encompass either vaginal or caesarean section – these five women were aiming for a vaginal birth but would opt for a caesarean section if needed augmentation during labour (1 woman) or induction of labour for post-dates (4 women).

Of the 105 women who had a vaginal study birth, 94.3% had a spontaneous vaginal birth (99/105), 3.8% had a vaginal birth assisted by kiwi (4/105) and 1.9% had a vaginal birth assisted by forceps (2/105). For the women who had a caesarean section study birth, 84.3% had an elective caesarean section (59/70), 10.0% had an emergency caesarean section during labour (7/70) and 5.7% had an emergency caesarean section prior to labour (4/70). Table 4.13 shows the actual mode of the study birth in relation to the initial OASIS classification for the 175 women recruited to the study. More women with a 3A (33.3% vs 21.4%) or unspecified OASIS (25.7% vs 22.9%) had a vaginal birth than a caesarean section. However, for both 3B (30.5% vs 37.1%) or 3C (10.5% vs 18.6%) OASIS classifications a higher number of women had a caesarean than a vaginal birth.

Table 4.13 Actual mode of study birth in relation to the initial OASIS classification

	Vaginal birth, n= 105				Caesarean section, n=70				
	SVD	Kiwi	Forceps	Total	Elective caesarean section	Emergency caesarean section – prior to labour	Emergency caesarean section – during labour	Total	Total
Previous OASIS classification, n (%)									
3A	34 (34.3)	0	1(50.0)	35	14 (23.7)	0	1 (14.2)	15 (21.4)	50
3B	30 (30.3)	1(25.0)	1 (50.0)	32	21 (35.6)	3 (75.0)	2 (28.6)	26 (37.1)	58
3C/4	9 (9.1)	2 (50.0)	0	11	11 (18.6)	0	2 (28.6)	13 (18.6)	24
Unspecified	26 (26.3)	1 (25.0)	0	27	13 (22.0)	1 (25.0)	2 (28.6)	16 (22.9)	43
Total	99 (100)	4 (100)	2 (100)	105 (100)	59 (100)	4 (100)	7 (100)	70 (100)	175

4.11.5 Bowel function following study birth

Table 4.14 shows the incidence of bowel symptoms at the time of the postnatal MHQ completion following the study birth. There were 76.8% (96/125) of the women who reported having experienced an episode of bowel urgency and 56.0% (70/125) of the women reported having poor control of flatus at any time. Difficulty in wiping clean was experienced by 34.4% (43/125) of the women. For the three bowel symptoms of bowel urgency, poor control of flatus and difficulty with wiping clean, of the women reporting these symptoms, these were experienced in each of the four frequency categories. Unlike the symptoms of bowel urgency and poor control of flatus, for the bowel symptom of difficulty in wiping a greater number of women never experienced this compared to the number who had an episode of this.

With regard to faecal leakage 23.2 % (29/125) of the women reported having had any episode of faecal leakage. Passive leakage was rare, reported by only 3% (4/125) of the women. Faecal leakage occurred more often with activity. The most common activity occurrence was leakage with coughing/sneezing with 13.6% (17/125) of the women experiencing this at some time. Faecal leakage with walking was experienced by 4% (5/125) of the women and faecal leakage during sexual intercourse was experienced by 1.6% (3/125) of the women. No woman reported faecal leakage as occurring Most/All of the time. All reported faecal leakage was of loose stools with no women ever experiencing any leakage of solid stools.

Table 4.14 Bowel symptoms at postnatal MHQ completion

				Faecal Leakage						
N=125	Bowel urgency	Difficulty wiping clean	Poor control of flatus	Faecal leakage - passive only	Faecal leakage with coughing/ sneezing	Faecal leakage with walking	Faecal leaking during SI	Faecal leakage – loose stool	Faecal leakage – solid stool	Any faecal leakage
Frequency of postnatal bowel symptom, n (%)										
Never	29 (23.2)	82 (65.6)	55 (44.0)	121 (96.8)	108 (86.4)	120 (96.0)	123 (98.4)	107 (85.6)	125 (100)	96 (76.8)
Occasionally	57 (45.6)	20 (16.0)	38 (30.4)	3 (2.4)	12 (9.6)	5 (4.0)	3 (1.6)	10 (8.0)	0	29 (23.2)
Sometimes	30 (24.0)	10 (8.0)	19 (15.2)	1 (0.8)	5 (4.0)	0	0	5 (4.0)	0	
Most of the time	8 (6.4)	9 (7.2)	11 (8.8)	0	0	0	0	2 (1.6)	0	
All of the time	1 (0.8)	4 (3.2)	2 (1.6)	0	0	0	0	1 (0.8)	0	

A comparison of bowel function for each of the nine bowel symptoms as captured by the MHQ prior to and following the study birth of any mode, was performed (Tables 4.15 – 4.22), to investigate whether at six months the women reported a worsening, no change or improvement in their bowel function.

Table 4.23 summarises the number of women reporting worsening, no change or improvement in the frequency of occurrence for each of the bowel symptoms at postnatal MHQ completion compared to the frequency when the MHQ was initially completed prior to the study birth. For all of the bowel symptoms except leakage during sexual intercourse, the proportion of women who had an improved frequency of symptom occurrence following the study birth was higher than the proportion who had a worsening. For leaking during sexual intercourse, two women had a worsening (1.6%) and one woman had an improvement (0.8%). Just under half of the women in the study had no change in bowel urgency (46.4%), following the study birth and just over half of the women (56.0%) had no change in the frequency of poor control of flatus. The occurrence of difficulty in wiping clean remained the same for 92.8% (116/125) of the women following the study birth. With regard to faecal leakage, 68% or more of the women reported no change in this bowel symptom, regardless of whether it was leakage with activity (coughing/sneezing, walking, sexual intercourse) or passive only.

Table 4.15 Comparison of bowel urgency at antenatal MHQ completion and at postnatal MHQ completion

	Bowel Urgency *At postnatal questionnaire completion*					
N=125, n (%)	Never	Occasionally	Sometimes	Most of the time	All of the time	Total
At antenatal questionnaire completion						
Never	14 (48.3)	8 (14.0)	6 (20.0)	0	0	28 (22.4)
Occasionally	11 (37.9)	28 (49.1)	10 (33.3)	1 (12.5)	0	50 (40.0)
Sometimes	4 (13.8)	20 (35.1)	12 (40.0)	3 (37.5)	0	39 (31.2)
Most of the time	0	1 (1.8)	2 (6.7)	3 (37.5)	0	6 (4.8)
All of the time	0	0	0	1 (12.5)	1 (100.0)	2 (1.6)
Total	29 (100)	57 (100)	30 (100)	8 (100)	1 (100)	125 (100.0)

Table 4.16 Comparison of poor control of flatus at antenatal MHQ completion and at postnatal MHQ completion

	Poor control of flatus *At postnatal questionnaire completion*					
N=125, n (%)	Never	Occasionally	Sometimes	Most of the time	All of the time	Total
At antenatal questionnaire completion						
Never	37 (67.3)	11 (28.9)	2 (10.5)	2 (18.2)	1 (50.0)	53 (42.4)
Occasionally	15 (27.3)	20 (52.6)	3 (15.8)	0	0	38 (30.4)
Sometimes	2 (3.6)	4 (10.5)	8 (42.1)	4 (36.4)	0	18 (14.4)
Most of the time	1 (1.8)	3 (7.9)	6 (31.6)	4 (36.4)	0	14 (11.2)
All of the time	0	0	0	1 (9.1)	1 (50.0)	2 (1.6)
Total	55 (100)	38 (100)	19 (100)	11 (100)	2 (100)	125 (100)

Table 4.17 Comparison of difficulty wiping clean at antenatal MHQ completion and at postnatal MHQ completion

	Difficulty wiping clean *At postnatal questionnaire completion*					
N=125, n (%)	Never	Occasionally	Sometimes	Most of the time	All of the time	Total
At antenatal questionnaire completion						
Never	64 (78.0)	4 (20.0)	3 (30.0)	2 (22.2)	0	73 (58.4)
Occasionally	14 (17.1)	13 (65.0)	2 (20.0)	1 (11.1)	0	30 (24.0)
Sometimes	4 (4.9)	2 (10.0)	3 (30.0)	1 (11.1)	1 (25.0)	11 (8.8)
Most of the time	0	1 (5.0)	2 (20.0)	4 (44.4)	2 (50.0)	9 (7.2)
All of the time	0	0	0	1 (11.1)	1 (25.0)	2 (1.6)
Total	82 (100)	20 (100)	10 (100)	9 (100)	4 (100)	125 (100)

Table 4.18 Comparison of faecal leakage – passive only at antenatal MHQ completion and at postnatal MHQ completion

	Faecal leakage – passive only *At postnatal questionnaire completion*					
N=125, n (%)	Never	Occasionally	Sometimes	Most of the time	All of the time	Total
At antenatal questionnaire completion						
Never	116 (95.9)	0	2 (66.7)	0	0	118 (94.4)
Occasionally	4 (3.3)	0	1 (33.3)	0	0	5 (4.0)
Sometimes	1 (0.8)	0	0	1(100.00)	0	2 (1.6)
Most of the time	0	0	0	0	0	0
All of the time	0	0	0	0	0	0
Total	121 (100)	0	3 (100)	1 (100)	0	125 (100)

Table 4.19 Comparison of faecal leakage when coughing/sneezing at antenatal MHQ completion and at postnatal MHQ completion

	Faecal leakage when coughing/sneezing *At postnatal questionnaire completion*					
N=125, n (%)	Never	Occasionally	Sometimes	Most of the time	All of the time	Total
At antenatal questionnaire completion						
Never	98 (90.7)	6 (50.0)	3 (60.0)	0	0	107 (85.6)
Occasionally	9 (8.3)	2 (16.7)	2 (40.0)	0	0	13 (10.4)
Sometimes	0	3 (25.0)	0	0	0	3 (2.4)
Most of the time	1 (0.9)	1 (8.3)	0	0	0	2 (1.6)
All of the time	0	0	0	0	0	0
Total	108 (100)	12 (100)	5 (100)	0	0	125 (100)

Table 4.20 Comparison of faecal leakage with walking at antenatal MHQ completion and at postnatal MHQ completion

	Faecal leakage with walking *At postnatal questionnaire completion*					
N=125, n (%)	Never	Occasionally	Sometimes	Most of the time	All of the time	Total
At antenatal questionnaire completion						
Never	115 (95.8)	3 (60.0)	0	0	0	118 (94.4)
Occasionally	3 (2.5)	1 (20.0)	0	0	0	4 (3.2)
Sometimes	2 (1.7)	1 (20.0)	0	0	0	3 (2.4)
Most of the time	0	0	0	0	0	0
All of the time	0	0	0	0	0	0
Total	120 (100)	5 (100)	0	0	0	125 (100)

Table 4.21 Comparison of faecal leakage during SI at antenatal MHQ completion and at postnatal MHQ completion

	Faecal leakage during SI *At postnatal questionnaire completion*					
N=125, n (%)	Never	Occasionally	Sometimes	Most of the time	All of the time	Total
At antenatal questionnaire completion						
Never	122 (99.2)	0	2 (1.6)	0	0	124 (99.2)
Occasionally	1 (0.8)	0	0	0	0	1 (0.8)
Sometimes	0	0	0	0	0	0
Most of the time	0	0	0	0	0	0
All of the time	0	0	0	0	0	0
Total	123 (100)	0	2 (100)	0	0	125 (100)

Table 4.22 Comparison of faecal leakage - loose at antenatal MHQ completion and at postnatal MHQ completion

	Faecal leakage – loose stools *At postnatal questionnaire completion*					
N=125, n (%)	Never	Occasionally	Sometimes	Most of the time	All of the time	Total
At antenatal questionnaire completion						
Never	94 (87.9)	2 (20.0)	2 (40.0)	0	1 (100.00)	99 (79.2)
Occasionally	7 (6.5)	6 (60.0)	0	2 (100.00)	0	15 (12.0)
Sometimes	5 (4.7)	1 (10.0)	3 (60.0)	0	0	9 (7.2)
Most of the time	0	1 (10.0)	0	0	0	1 (0.8)
All of the time	1 (0.9)	0	0	0	0	1 (0.8)
Total	107 (100)	10 (100)	5 (100)	2 (100)	1 (100)	125 (100)

Table 4.23 Comparison of bowel symptoms at postnatal MHQ completion and at antenatal MHQ completion

	Postnatal MHQ bowel frequency compared to antenatal MHQ bowel frequency		
Bowel symptom, N=125, n (%)	Worsened	No change	Improved
Bowel urgency	28 (22.4)	58 (46.4)	39 (31.2)
Poor control of flatus	23 (18.4)	70 (56.0)	32 (25.6)
Difficulty with wiping clean	3 (2.4)	116 (92.8)	6 (4.8)
Faecal Leakage – passive only	3 (2.4)	117 (93.6)	5 (4.0)
Faecal leakage with coughing/sneezing	11 (8.8)	100 (80.0)	14 (11.2)
Faecal leakage with walking	16 (0.8)	85 (68.0)	24 (19.2)
Faecal leakage with SI	2 (1.6)	122 (97.6)	1 (0.8)
Faecal leakage – loose stools	7 (5.6)	103 (82.4)	15 (12.0)
Any faecal leakage	13 (10.4)	96 (76.8)	16 (12.8)

4.11.6 QoL scores following subsequent birth

The QoL scores for all of the women who completed the postnatal MHQ following the study birth (n=125) are detailed in table 4.24. The mean scores for the nine QoL domains ranged from 2.9 [±10.8] for the domain of 'Social Limitations' to 16.0 [± 22.1] for the domain of 'Incontinence Impact' on their life. Across the nine QoL domains 20.8-90.4% of the women found their bowel function at postnatal MHQ completion had no effect on their QoL.

Table 4.24 Postnatal MHQ QoL domain scores

	MHQ QoL domain, n (%)															
Postnatal MHQ QoL domain scores N=125	General Health Perception		Incontinence Impact		Role Limitations		Physical Limitations		Social Limitations		Personal Relationships		Emotions		Sleep / Energy		Severity Measures	
Mean score, [SD}	12.8	[15.1]	16.0	[22.1]	12.7	[10.0]	3.7	[10.4]	2.9	[10.8]	3.2	[12.9]	9.7	[19.4]	3.5	[11.7]	6.9	[16.2]
Total score																		
0	68	(54.4)	68	(54.4)	26	(20.8)	105	(84.0)	110	(88.8)	113	(90.4)	84	(67.2)	109	(87.2)	90	(72.0)
1-25	50	(40.0)	43	(34.4)	90	(72.0)	16	(12.8)	11	(8.8)	9	(7.2)	25	(20.0)	13	(10.3)	36	(28.8)
26-50	7	(5.6)	7	(5.6)	9	(7.2)	3	(2.4)	3	(2.4)	1	(0.8)	11	(8.8)	1	(0.8)	5	(4.0)
51-75	0		5	(4.0)	0		1	(0.8)	0		1	(0.8)	3	(2.4)	2	(1.6)	5	(4.0)
76-100	0		2	(1.6)	0		0		1	(0.8)	1	(0.8)	2	(1.6)	0		2	(1.6)

One of the objectives of the study was to determine any changes in QoL for women with a previous OASIS following a subsequent birth: namely, worsening, no change or improvement. For the 125 women who completed the postnatal MHQ, a comparison of QoL scores for each of the nine QoL domains as captured by the MHQ prior to and following the study birth of any mode, was performed (Tables 4.25 - 4.33).

Table 4.34 summarises the number of women reporting a worsening, no change or improvement in the QoL scores for each of the QoL domains at postnatal MHQ completion (following the study birth), compared to the corresponding QoL domain score when the MHQ was initially completed antenatally (prior to the study birth). 'Role Limitation' was the only QoL domain whereby fewer women completing the questionnaire after their study birth had an improved score (9.6%, 12/125) compared to those who had a worsened score (13.6%, 17/125). For all other QoL domains there were a higher percentage of women having an improved score following the study birth than the percentage of women who had a worsened score. Across the nine QoL domains 4.0-15.2% of the women had a worsening in their QoL following the study birth; 57.6-86.4% of the women had no change in their QoL and 8.8-31.2% of women had an improvement.

Table 4.25 Comparison of MHQ General Health Perception (GHP) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal GHP QoL domain score									
N=125, n (%)	0		1-25		26-50		51-75	76-100	Total number of women	
Antenatal GHP QoL domain score										
0	41	(60.3)	10	(20.0)	0	(0.0)	0	0	51	(40.8)
1-25	23	(33.8)	29	(58.0)	4	(57.1)	0	0	56	(44.8)
26-50	4	(5.9)	10	(20.0)	2	(28.6)	0	0	16	(12.8)
51-75	0		1	(2.0)	1	(14.3)	0	0	2	(1.6)
76-100	0		0		0		0	0	0	
Total number of women	68	(100)	50	(100)	7	(100)	0	0	125	(100)

Table 4.26 Comparison of MHQ Incontinence Impact (II) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal II QoL domain score											
N=125, n (%)	0		1-25		26-50		51-75		76-100		Total number of women	
Antenatal II QoL domain score												
0	53	(77.9)	12	(27.9)	1	(14.3)	1	(20.0)	0		67	(53.6)
1-25	13	(19.1)	21	(48.8)	1	(14.3)	0		0		35	(28.0)
26-50	1	(1.5)	7	(16.3)	4	(57.1)	2	(40.0)	0		14	(11.2)
51-75	1	(1.5)	3	(7.0)	1	(14.3)	1	(20.0)	2	(1.6)	8	(6.4)
76-100	0		0		0		1	(20.0)	0		1	(0.8)
Total number of women	68	(100)	43	(100)	7	(100)	5	(100)	2	(100)	125	(100)

Table 4.27 Comparison of MHQ Role Limitations (RL) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal RL QoL domain score									
N=125, n (%)	0		1-25		26-50		51-75	76-100	Total number of women	
Antenatal RL QoL domain score										
0	19	(73.1)	11	(12.2)	2	(14.3)	0	0	32	(25.6)
1-25	7	(26.9)	74	(82.2)	4	(14.3)	0	0	85	(68.0)
26-50	0		4	(4.4)	3	(57.1)	0	0	7	(5.6)
51-75	0		1	(1.1)	0	(14.3)	0	0	1	(0.8)
76-100	0		0		0		0	0	0	
Total number of women	26	(100)	90	(100)	9	(100)	0	0	125	(100)

Table 4.28 Comparison of MHQ Physical Limitations (PL) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal PL QoL domain score										Total number of women	
N=125, n (%)	0		1-25		26-50		51-75		76-100			
Antenatal PL QoL domain score												
0	92	(87.6)	6	(37.5)	1	(33.3)	0		0		99	(79.2)
1-25	7	(6.7)	6	(37.5)	1	(33.3)	0		0		14	(11.2)
26-50	6	(5.7)	4	(25.0)	1	(33.3)	0		0		11	(8.8)
51-75	0		0		0		1	(100.0)	0		1	(0.8)
76-100	0		0		0		0		0		0	
Total number of women	105	(100)	16	(100)	3	(100)	1	(100)	0		125	(100)

Table 4.29 Comparison of MHQ Social Limitations (SL) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal SL QoL domain score											
N=125, n (%)	0		1-25		26-50		51-75		76-100	Total number of women		
Antenatal SL QoL domain score												
0	100	(90.9)	5	(45.5)	1	(33.3)	0		0	106	(84.8)	
1-25	9	(8.2)	5	(45.5)	1	(33.3)	0		0	15	(12.0)	
26-50	1	(0.9)	1	(9.1)	1	(33.3)	0		0	3	(2.4)	
51-75	0		0		0		1	(100.0)	0	1	(0.8)	
76-100	0		0		0		0		0	0		
Total number of women	110	(100)	11	(100)	3	(100)	1	(100)	0	125	(100)	

Table 4.30 Comparison of MHQ Personal Relationships (PR) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal PR QoL domain score											
N=125, n (%)	0		1-25		26-50		51-75		76-100		Total number of women	
Antenatal PR QoL domain score												
0	103	(91.2)	5	(55.6)	1	(100.0)	0		0		109	(87.2)
1-25	10	(8.8)	3	(33.3)	0		0		1	(100.0)	14	(11.2)
26-50	0		1	(11.1)	0		0		0		1	(0.8)
51-75	0		0		0		1	(100.0)	0		1	(0.8)
76-100	0		0		0		0		0		0	
Total number of women	114	(100)	9	(100)	1	(100)	1	(100)	0	(100)	125	(100)

Table 4.31 Comparison of MHQ Emotions (E) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal E QoL domain score											
N=125, n (%)	0		1-25		26-50		51-75		76-100		Total number of women	
Antenatal E QoL domain score												
0	72	(85.7)	7	(28.0)	1	(9.1)	0		0		80	(64.0)
1-25	9	(10.7)	13	(52.0)	3	(27.3)	0		0		25	(20.0)
26-50	2	(2.4)	3	(12.0)	7	(63.6)	2	(66.7)	0		14	(11.2)
51-75	1	(1.2)	2	(8.0)	0		0		1	(50.0)	4	(3.2)
76-100	0		0		0		1	(33.3)	1	(50.0)	2	(1.6)
Total number of women	84	(100)	25	(100)	11	(100)	3	(100)	2	(100)	125	(100)

Table 4.32 Comparison of MHQ Sleep/Energy (SE) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal SE QoL domain score											
N=125, n (%)	0		1-25		26-50		51-75		76-100		Total number of women	
Antenatal SE QoL domain score												
0	100	(91.7)	5	(38.5)	0		0		0		105	(84.0)
1-25	7	(6.4)	5	(38.5)	0		0		0		12	(9.6)
26-50	2	(1.8)	3	(23.1)	1	(100.0)	0		0		6	(4.8)
51-75	0		0		0		2	(100.0)	0		2	(1.6)
76-100	0		0		0		0		0		0	
Total number of women	109	(100)	13	(100)	1	(100)	2	(100)	0		125	(100)

Table 4.33 Comparison of MHQ Severity Measure (SM) QoL domain scores at antenatal questionnaire completion and at postnatal questionnaire completion

	Postnatal SM QoL domain score											
N=125, n (%)	0		1-25		26-50		51-75		76-100		Total number of women	
Antenatal SM QoL domain score												
0	71	(78.9)	7	(26.9)	1	(20.0)	0		0		79	(63.2)
1-25	19	(21.1)	13	(50.0)	0		0		0		32	(25.6)
26-50	0		3	(11.5)	3	(60.0)	2	(100.0)	1	(50.0)	9	(7.2)
51-75	0		3	(11.5)	1	(20.0)	0		0		4	(3.2)
76-100	0		0		0		0		1	(50.0)	1	(0.8)
Total number of women	90	(100)	26	(100)	5	(100)	2	(100)	2	(100)	125	(100)

Table 4.34 Comparison of QoL domain scores at postnatal MHQ completion and at antenatal MHQ completion

	Postnatal MHQ QoL domain scores compared to antenatal MHQ QoL domain scores		
QoL domain, N=125, n (%)	Worsened	No change	Improved
General Health Perception (GHP)	14 (11.2)	72 (57.6)	39 (31.2)
Incontinence Impact (II)	19 (15.2)	79 (63.2)	27 (21.6)
Role Limitations (RL)	17 (13.6)	96 (76.8)	12 (9.6)
Physical Limitations (PL)	8 (6.4)	100 (80.0)	17 (13.6)
Social Limitations (SL)	7 (5.6)	107 (85.6)	11 (8.8)
Personal Relationships (PR)	7 (5.6)	107 (85.6)	11 (8.8)
Emotions (E)	14 (11.2)	93 (74.4)	18 (14.4)
Sleep/Energy (S/E)	5 (4.0)	108 (86.4)	12 (9.6)
Severity Measure (SM)	11 (8.8)	88 (70.4)	26 (20.8)

4.11.7 Mode of study birth on bowel function and QoL

One of the main aims of the study was to investigate effect of the mode of subsequent birth on bowel function and QoL for women who had previously sustained an OASIS. Of the 175 women recruited to the study 60% (105/175) had a vaginal birth and 40% (70/175) of the women had a caesarean section and table 4.35 shows the comparison of the baseline maternal, OASIS characteristics/ labour, study birth and neonatal characteristics between these two groups.

Baseline maternal characteristics of age at OASIS, time between OASIS birth and antenatal MHQ completion, ethnicity and parity at recruitment to the study were comparable. However, there was a significant difference between the two groups for BMI and women who had had a vaginal interval birth. Women undergoing a caesarean section for their study birth had a slightly higher BMI, and a much higher proportion of women undergoing a vaginal study birth had had a vaginal interval birth. In relation to the OASIS birth, trauma classification, method of repair and mode of OASIS birth were comparable between the two groups. Neonatal characteristics at the OASIS birth of gestational age, birth weight and head circumference were all comparable between the two groups.

In relation to the characteristics of the study birth, the number of women requesting the mode to be vaginal or caesarean section was comparable across the two groups, as was the number of women achieving their desired mode of study birth. However, as to be expected a much higher proportion of women undergoing a caesarean

section for the study birth had bowel symptoms and anal sphincter defects detected during antenatal EAUS.

Table 4.35 Baseline maternal characteristics – study birth mode vaginal birth or caesarean section

Characteristics, n, (%)	Vaginal birth n=105 (60.0)	Caesarean section n=70 (40.0)	*p*-value
Maternal characteristics			
Age at OASIS birth (years), mean [SD]	27.7 [4.7]	28.0 [4.4]	0.653
Time between OASIS birth and antenatal questionnaire completion (years), mean [SD]	4.29 [3.39]	3.94 [3.94]	0.460
Ethnicity			0.260
White	47 (44.8)	38 (54.3)	
Mixed/Multiple	1 (0.9)	1 (1.4)	
Asian/Asian British	35 (33.3)	25 (35.7)	
Black/African/Caribbean/Black British	17 (16.2)	5 (7.2)	
Other/Not Known	5 (4.8)	1 (1.4)	
BMI, mean [SD]	25.8 [5.3]	27.8 [6.0]	*0.031*
Parity at recruitment			0.469
1	73 (69.5)	53 (75.7)	
2	25 (23.8)	15 (21.4)	
≥3	7 (6.7)	2 (2.9)	
Vaginal interval birth	26 [24.8]	3 [4.3]	*<0.001*
OASIS birth characteristics			
OASIS classification			0.188
3A	35 (33.3)	15 (21.4)	
3B	32 (30.5)	26 (37.1)	
3C/4	11 (10.5)	13 (18.6)	
Unspecified	27 (25.7)	16 (22.9)	
Method of repair			0.433
End-to-end	46 (43.8)	26 (37.1)	
Overlap	28 (26.7)	25 (35.7)	
Unspecified	31 (29.5)	19 (27.2)	
Mode of OASIS birth			0.131
SVD	69 (65.7)	36 (51.4)	
Kiwi/ventouse	11 (10.5)	6 (8.6)	
Low/unspecified forceps	21 (20.0)	25 (35.7)	
Rotational forceps	4 (3.8)	3 (4.3)	
Neonatal characteristics for OASIS birth			
Gestational age, (weeks), median [IQR]¥	40 [39, 40]	40 [39,40]	0.529
Birth weight, (kg), mean [SD]	3.404 [0.586]	3.513 [0.606]	0.237
Head circumference (cms), mean [SD]	33.8 [4.2]	34.5 [1.7]	0.214
Study birth characteristics			
Maternal request for mode of birth	91 (86.7)	63 (90.0)	0.506
Bowel symptoms	1 (0.9)	19 (27.1)	*<0.001*
Requested mode of study birth achieved ✞	102 (97.1)	63 (90.0)	0.091
Anal sphincter defect on antenatal EAUS	3 (2.9)	38 (54.3)	*<0.001*

✞ excludes the five women who were pursuing either a vaginal or caesarean section depending on clinical events

Table 4.36 shows the comparison of the bowel function at antenatal MHQ completion between study participants whose mode of study birth was vaginal (n=105) and those women whose study birth was by caesarean section (n=70). Bowel function at antenatal questionnaire completion between the two groups was comparable for difficulty wiping clean, leakage – passive only, leakage with coughing/sneezing, leakage with walking, leakage during SI, loose leakage, solid leakage and any bowel leakage. The only significant differences were for bowel urgency and control of flatus, with more women whose study birth was by caesarean section having both bowel urgency and poor control of flatus at the time of antenatal MHQ completion.

Table 4.36 Baseline bowel function at antenatal MHQ completion – study birth mode vaginal birth or caesarean section

Characteristics, n (%)	Vaginal birth n=105 (60.0)	Caesarean section n=70 (40.0)	*p*-value
Bowel function at antenatal questionnaire completion			
Bowel urgency			
Never	33 (31.4)	11 (15.7)	*<0.001*
Occasionally	47(44.8)	22 (31.4)	
Sometimes	19 (18.1)	31 (44.3)	
Most of the time	6 (5.7)	4 (5.8)	
All of the time	0	2 (2.9)	
Difficulty wiping clean			0.172
Never	69 (65.4)	41 (58.6)	
Occasionally	23 (21.4)	12 (17.1)	
Sometimes	6 (5.7)	9 (12.9)	
Most of the time	7 (6.7)	6 (8.6)	
All of the time	0	2 (2.9)	
Poor control of flatus			*0.012*
Never	61 (58.1)	30 (42.9)	
Occasionally	30 (28.6)	15 (21.4)	
Sometimes	7 (6.7)	13 (18.6)	
Most of the time	6 (5.7)	9 (12.9)	
All of the time	1 (0.9)	3 (4.3)	
Faecal leakage- passive only			1.000
Never	100 (95.2)	67 (95.7)	
Occasionally	3 (2.9)	2 (2.9)	
Sometimes	2 (1.9)	1 (1.4)	
Most of the time	0	0	
All of the time	0	0	
Faecal leakage with coughing/sneezing			0.218
Never	93 (88.6)	57 (81.3)	
Occasionally	8 (7.6)	9 (12.9)	
Sometimes	4 (3.8)	2 (2.9)	
Most of the time	0	2 (2.9)	
All of the time	0	0	
Faecal leakage with walking			0.514
Never	101 (96.2)	66 (94.3)	
Occasionally	1 (0.9)	3 (4.3)	
Sometimes	3 (2.9)	1 (1.4)	
Most of the time	0	0	
All of the time	0	0	
Faecal leakage during SI			0.159
Never	104 (99.1)	68 (97.1)	
Occasionally	0	2 (2.9)	
Sometimes	1 (0.9)	0	
Most of the time	0	0	
All of the time	0	0	
Faecal leakage – loose stools			
Never	85 (80.9)	56 (80.0)	0.535
Occasionally	11 (10.5)	8 (11.4)	
Sometimes	5 (4.8)	6 (8.6)	
Most of the time	3 (2.9)	0	
All of the time	1 (0.9)	0	
Faecal leakage – solid stools			
Never	105 (100.0)	70 (100.0)	
Any faecal leakage			0.597
Yes	80 (76.2)	50 (71.4)	
No	25 (23.8)	20 (28.6)	

Table 4.37 shows the comparison of the baseline QoL domain scores at antenatal MHQ completion between participants whose mode of study birth was vaginal (n=105) and those women whose study birth was by caesarean section (n=70). The antenatal scores for the QoL domains of 'General Health Perception', 'Role Limitations', 'Physical Limitations', 'Social Limitations', 'Personal Relationships', 'Emotions' and 'Sleep/Energy', were comparable between the two groups. However, more women whose study birth was by caesarean section had QoL domain scores reflecting a negative impact from bowel function on their QoL for the two domains of 'Incontinence Impact' and 'Severity Measure'.

Table 4.37 Baseline QoL score at antenatal MHQ completion – study birth mode vaginal birth or caesarean section

Characteristics, n (%)	Vaginal birth n=105 (60.0)	Caesarean section n=70 (40.0)	*p*-value
QoL domain scores at antenatal questionnaire completion			
General Health Perception (GHP)			0.130
0	49 (46.7)	23 (32.9)	
1-25	42 (40.0)	39 (55.7)	
26-50	12 (11.4)	8 (11.4)	
51-75	2 (1.9)	0	
76-100	0	0	
Incontinence Impact (II)			*0.001*
0	72 (68.5)	29 (41.4)	
1-25	21 (20.0)	28 (40.0)	
26-50	5 (4.8)	10 (14.3)	
51-75	5 (4.8)	3 (4.3)	
76-100	2 (1.9)	0	
Role Limitations (RL)			0.286
0	28 (26.7)	19 (27.1)	
1-25	72 (68.5)	45 (64.3)	
26-50	3 (2.9)	6 (8.6)	
51-75	2 (0.9)	0	
76-100	0	0	
Physical Limitations (PL)			0.673
0	89 (84.8)	56 (80.0)	
1-25	9 (8.6)	7 (64.3)	
26-50	6 (5.7)	6 (8.6)	
51-75	1 (0.9)	0	
76-100	0	1 (1.4)	
Social Limitations (SL)			0.177
0	94 (89.5)	59 (84.3)	
1-25	7 (6.7)	10 (14.3)	
26-50	3 (2.9)	0	
51-75	0	0	
76-100	1 (0.9)	1 (1.4)	
Personal Relationships (PR)			0.841
0	95 (90.5)	63 (90.0)	
1-25	8 (7.6)	6 (8.6)	
26-50	0	1 (1.4)	
51-75	1 (0.9)	0	
76-100	1 (0.9)	0	
Emotions (E)			0.052
0	82 (78.0)	43 (61.5)	
1-25	13 (12.4)	15 (21.4)	
26-50	5 (4.8)	10 (14.3)	
51-75	3 (2.9)	1 (1.4)	
76-100	2 (1.9)	1 (1.4)	
Sleep/Energy (SE)			0.225
0	94 (89.5)	56 (80.0)	
1-25	6 (5.7)	10 (14.3)	
26-50	3 (2.9)	3 (4.3)	
51-75	2 (1.9)	1 (1.4)	
76-100	0	0	

Severity Measure (SM)			*0.008*
0	75 (71.4)	44 (62.8)	
1-25	25 (23.4)	15 (21.4)	
26-50	1 (0.9)	9 (12.9)	
51-75	2 (2.9)	2	
76-100	2 (1.9)	0	

For the 125 women who completed a postnatal MHQ a comparison of bowel function for each of the nine MHQ bowel symptoms prior to and following the study birth by mode of birth (either vaginal or caesarean section), was performed (Table 4.38). This was undertaken to investigate whether the actual mode of the study birth was a factor contributing to any change in bowel function for women at six months following the study birth.

For all of the nine bowel symptoms there was no significant association between the mode of study birth, either vaginal or caesarean section and a worsening, no change or improvement of frequency of their symptom occurrence (Table 4.38).

Table 4.38 Comparison of changes in bowel symptom frequency prior to and following study birth by mode of birth

	Mode of study birth – vaginal (n=74)			Mode of study birth – caesarean section (n=51)			
	Postnatal MHQ bowel frequency compared to antenatal MHQ bowel frequency			Postnatal MHQ bowel frequency compared to antenatal MHQ bowel frequency			
	Worsened	No change	Improved	Worsened	No change	Improved	*p* value[↗]
Bowel function following study birth, n (%)							
Bowel urgency	20 (27.0)	34 (46.0)	20 (27.0)	8 (15.7)	24 (47.1)	19 (37.2)	0.265
Poor control of flatus	15 (20.3)	41 (55.4)	18 (24.3)	8 (15.7)	29 (56.9)	14 (27.4)	0.800
Difficulty with wiping clean	2 (2.7)	69 (93.2)	3 (4.1)	1 (2.0)	47 (92.2)	3 (5.8)	0.865
Faecal Leakage – passive only	1 (1.4)	69 (93.2)	4 (5.4)	2 (3.9)	48 (94.1)	1 (2.0)	0.530
Faecal leakage with coughing/sneezing	8 (10.8)	61 (82.4)	5 (6.8)	3 (5.8)	39 (76.5)	9 (17.7)	0.124
Faecal leakage with walking	8 (10.8)	52 (70.3)	14 (18.9)	8 (15.7)	33 (64.7)	10 (19.6)	0.701
Faecal leakage with SI	2 (2.7)	72 (97.3)	0	0	50 (98.0)	1 (2.0)	0.309
Faecal leakage – loose stools	3 (4.1)	64 (86.5)	7 (9.4)	4 (7.8)	39 (76.5)	8 (15.7)	0.333
Faecal leakage - any	9 (12.2)	58 (78.4)	7 (9.4)	4 (7.8)	38 (74.5)	9 (17.7)	0.345

[↗] Fischer's exact test

To investigate whether the mode of the study birth was a factor contributing to any change in QoL for women at six months postpartum, a comparison of the MHQ QoL scores at both time points by mode of birth (either vaginal or caesarean section) was performed (Table 4.39).

For all of the nine QoL domains there was no significant association between the mode of study birth, either vaginal or caesarean section and a worsening, no change or improvement in QoL (Table 4.39).

For women having a vaginal study birth there were two QoL domains whereby a greater proportion of women had worsening of the score in comparison to the number of women who had an improvement; namely 'Incontinence Impact' (18.9 vs 17.6%), and 'Role Limitations' (14.9 vs 8.1%). For the QoL domain of 'Emotions', the proportions of women having a worsened or improved score were the same at 14.9% (11/74). For all of the other six QoL domains there were a greater proportion of women who had an improved score than those who had a worsened score.

For women having a caesarean section study birth, apart from the QoL domain of 'Role Limitations' whereby the proportion of women having a worsened or improved score were the same at 11.8% (6/51), in all other QoL domains there were a greater proportion of women who had an improved score than those who had a worsened score.

Table 4.39 Comparison of changes in MHQ QoL scores prior to and following study birth by mode of birth

	Mode of study birth – vaginal (n=74)			Mode of study birth – caesarean section (n=51)			
	Postnatal MHQ QoL domain score compared to antenatal MHQ QoL domain score			Postnatal MHQ QoL domain score compared to antenatal MHQ QoL domain score			
	Worsened score	No change in score	Improved score	Worsened score	No change in score	Improved score	*p* value[➚]
MHQ QoL domain, n (%)							
General Health Perception (GHP)	9 (12.2)	43 (58.1)	22 (29.7)	5 (9.8)	29 (56.9)	17 (33.3)	0.897
Incontinence Impact (II)	14 (18.9)	47 (63.5)	13 (17.6)	5 (9.8)	32 (62.8)	14 (27.5)	0.235
Role Limitations (RL)	11 (14.9)	57 (77.0)	6 (8.1)	6 (11.8)	39 (76.5)	6 (11.8)	0.699
Physical Limitations (PL)	2 (2.7)	63 (85.1)	9 (12.2)	6 (11.8)	36 (70.6)	9 (17.7)	0.077
Social Limitations (SL)	4 (5.4)	64 (86.5)	6 (8.1)	3 (5.9)	43 (84.3)	5 (9.8)	0.927
Personal Relationships (PR)	5 (6.8)	63 (85.1)	6 (8.1)	2 (3.9)	43 (84.3)	6 (11.8)	0.691
Emotions (E)	11 (14.9)	52 (70.3)	11 (14.9)	3 (5.9)	41 (80.4)	7 (13.7)	0.292
Sleep/Energy (SE)	2 (2.7)	65 (87.8)	7 (9.5)	3 (5.9)	43 (84.3)	5 (9.8)	0.713
Severity Measure (SM)	5 (6.8)	55 (74.3)	14 (18.9)	6 (11.8)	33 (64.7)	12 (23.3)	0.421

[➚] Fischer's exact test

4.11.8 Endoanal scan findings following subsequent birth

As discussed in section 1.4 it is routine clinical practice at the NHS Trust in which the study was undertaken for all women who have previously sustained an OASIS to attend a specialist OASIS clinic for an endoanal ultrasound scan (EAUS) to be performed prior during any subsequent pregnancy to determine the integrity and presence of any extensive scarring or defects in the anal sphincter muscles. This information is then used as part of the mode of birth counselling consultation. As this study was designed to run seamlessly with routine clinical practice, as mentioned previously in section 4.7, all women were offered antenatal EAUS and 98.9% (173/175) of the women accepted and underwent this. Of these 173 women, 42 (24.3%) had excessive scarring or an anal sphincter defect visible with the remaining 131 women (75.7%) having no sphincter abnormality.

Of the 125 recruited women who completed the postnatal MHQ, 105 (84%) also underwent EAUS examination following the study birth. Table 4.40 shows changes in the EAUS findings. For all modes of study birth there was no change in EAUS findings for 92.4% (97/105) of the women. In the subgroup of 28 women who had either excessive scarring or an anal sphincter defect diagnosed as present following the study birth, 89.3% (25/28) of these women had also had either excessive scarring or an anal sphincter defect diagnosed prior to the study birth. Seventy two women (93.5%) had no sphincter abnormalities prior to or following the study birth.

Of the 105 women undergoing EAUS following the study birth 8 (7.6%) had changes diagnosed in sphincter muscle integrity; five of the women had no defects visible on

the post birth EAUS despite having defects diagnosed prior to the study birth and three women had defects visible following the study birth who did not have defects diagnosed prior to this. For the group of women who had newly found excessive scarring or defects, three of these women had caesarean section for the study birth mode and the remaining two women had a vaginal birth, one with a repeat OASIS (classification 3b). Of the three women whose post birth EAUS did not demonstrate the excessive scarring or defects that had been seen previously, all had vaginal births for the study birth mode with one of these women having a repeat OASIS (classification 3b).

Table 4.40 EAUS findings for women prior to and following the study birth

N=105, n (%)	*EAUS findings post subsequent birth*		
	No sphincter abnormality	Extensive scarring or defect present	Total
EAUS findings prior to subsequent birth			
No sphincter abnormality	72 (96.0)	5 (16.7)	77 (73.3)
Extensive scarring or defect present	3 (4.0)	25 (83.3)	28 (26.7)
Total	75 (100)	30 (100)	105 (100)

Further analysis was undertaken to explore if the presence or absence of extensive scarring or defect following the study birth was significantly associated with bowel symptoms at six months postnatally. Table 4.41 shows the number of women reporting the absence or presence of the bowel symptoms of bowel urgency poor control of flatus, faecal leakage – passive only and any faecal leakage at postnatal MHQ completion for women who did / did not have anal sphincter defect seen on EAUS following the study birth. Among these 105 women, the presence of excessive scarring or an anal sphincter defect on EAUS following the study birth was not significantly associated with any of the bowel symptoms of bowel urgency, poor control of flatus, faecal leakage – passive only and any faecal leakage (Table 4.41).

Table 4.41 Bowel function for women who had EAUS following subsequent birth – all modes of birth

	Women undergoing EAUS following study birth – all modes, N=105, n (%)		
Bowel symptom following study birth	No sphincter abnormality, n=77	Extensive scarring or defect present, n=28	*p* value[↗]
Bowel urgency	59 (76.6)	25 (89.3)	0.151
Poor control of flatus	41 (53.3)	18 (64.3)	0.313
Faecal leakage – passive only	2 (2.6)	2 (7.1)	0.282
Any faecal leakage	19 (24.7)	6 (21.4)	0.730

[↗] Fischer's exact test

Similar analysis was also undertaken to explore if the presence or absence of excessive scarring or an anal sphincter defect following the study birth was significantly associated with a negative impact on QoL at six months postnatally. Table 4.42 shows that the presence of excessive scarring or an anal sphincter defect on EAUS following the study birth was not significantly associated with a negative impact on any of the nine QoL domains (Table 4.42).

Table 4.42 Comparison of a negative impact on QoL following study birth by presence/absence of extensive scarring or defect – all modes of birth

	Women undergoing EAUS following study birth – all modes, N=105, n (%)		
MHQ QoL domain	No sphincter abnormality, n=77	Extensive scarring or defect present, n=28	*p* value[♂]
General Health Perception (GHP)	34 (54.2)	12 (42.9)	0.999
Incontinence Impact (II)	34 (54.2)	13 (46.4)	0.836
Role Limitations (RL)	62 (80.5)	22 (78.6)	0.825
Physical Limitations (PL)	10 (13.0)	8 (28.6)	0.061
Social Limitations (SL)	9 (11.7)	4 (14.3)	0.721
Personal Relationships (PR)	6 (7.8)	4 (14.3)	0.316
Emotions (E)	22 (28.6)	11 (39.3)	0.296
Sleep/Energy (SE)	8 (10.4)	6 (21.4)	0.141
Severity Measure (SM)	22 (28.6)	10 (35.7)	0.482

[♂] Fischer's exact test

One of the study objectives was to evaluate the association between mode of birth and anal sphincter muscle integrity on bowel function following a subsequent birth for women with previous OASIS. Therefore an analysis was undertaken on the data from the 105 women undergoing EAUS following the study birth to explore if the actual mode of the study birth was associated with any change in bowel function at six months following the study birth in women with a known anal sphincter abnormality or without. The 105 women who underwent postnatal EAUS were dichotomised into two groups of either 'no sphincter abnormality' or 'Extensive scarring or defect present'. A comparison of any changes in bowel symptoms as captured by the MHQ prior to and following the study birth depending of the mode of birth (either vaginal or caesarean section), was then performed for both of these groups.

The mode of study birth (vaginal or caesarean section) had no significant association for worsening, no change or improvement in symptoms whether an anal sphincter defect was present or not, for any of the four bowel symptoms (Table 4.43).

Table 4.43 Comparison of worsening, no change or improvement in bowel symptoms by the presence/absence of extensive scarring or defect following study birth – all modes of birth

		EAUS findings following subsequent study birth, N=105 (vaginal birth = 66, caesarean section = 39)							
		No sphincter abnormality, n=77, n (%)				Extensive scarring or defect present, n=28, n (%)			
		Postnatal MHQ bowel symptoms compared to antenatal MHQ bowel symptoms				Postnatal MHQ bowel symptoms compared to antenatal MHQ bowel symptoms			
Bowel function following study birth	Mode of study birth	Worsened	No change	Improved	*p* value [↗]	Worsened	No change	Improved	*p* value [↗]
Bowel Urgency	vaginal	19 (31.2)	26 (42.6)	16 (23.2)	0.724	1 (20.0)	3 (60.0)	1 (20.0)	1.000
	caesarean section	4 (25.0)	6 (37.5)	6 (37.5)		4 (17.4)	12 (52.2)	7 (30.4)	
Poor control of flatus	vaginal	11 (18.0)	34 (55.7)	16 (23.2)	0.238	2 (40.0)	2 (40.0)	1 (20.0)	0.806
	caesarean section	2 (12.5)	6 (37.5)	8 (50.0)		5 (21.7)	13 (56.5)	5 (21.7)	
Faecal leakage – passive only	vaginal	1 (1.6)	57 (93.4)	3 (4.9)	0.498	0	4 (80.0)	1 (20.0)	0.331
	caesarean section	1 (6.3)	14 (87.5)	1 (6.3)		1 (4.4)	22 (95.7)	0	
Any faecal leakage	vaginal	8 (13.1)	49 (80.3)	4 (6.6)	0.313	0	4 (80.0)	1 (20.0)	1.000
	caesarean section	1 (6.3)	12 (75.0)	3 (18.8)		1 (4.4)	19 (82.6)	3 (13.0)	

[↗] Fischer's exact test

Clinical experience confirms that for women with previous OASIS, their main concern when deciding on the mode of a subsequent birth is the possibility of any worsening of existing bowel symptoms. This was demonstrated by the reasons given by women in the study for choosing a caesarean section for the subsequent birth (section 4.10.4, table 4.11). Therefore, further analysis was undertaken whereby changes in bowel symptoms were dichotomised into two groups of 'worsening' or 'no worsening'.

For the 105 women who underwent post study birth EAUS, the mode of study birth (vaginal birth or caesarean section) had no significant association for worsening or no worsening in symptoms whether an anal sphincter defect was present or not, for any of the four bowel symptoms (Table 4.44).

Table 4.44 Comparison of worsening or no worsening in bowel symptoms by the presence/absence of extensive scarring or defect following study birth – all modes of birth

		EAUS findings post subsequent birth, N=105 (vaginal birth = 66, caesarean section = 39)					
		No anal sphincter defect, n=77, n (%)			Anal sphincter defect present, n=28, n (%)		
Bowel function following study birth	Mode of study birth	Worsening	No worsening	*p* value[↗]	Worsening	No worsening	*p* value[↗]
Bowel Urgency	vaginal	19 (31.1)	42(68.9)	0.764	1 (20.0)	4 (80.0)	1.000
	caesarean section	4 (25.0)	12 (75.0)		4 (17.4)	19 (82.6)	
Poor control of flatus	vaginal	11 (18.0)	50 (82.0)	0.725	2 (40.0)	3 (60.0)	0.574
	caesarean section	2 (12.5)	14 (87.5)		5 (21.7)	18 (78.3)	
Faecal leakage – passive only	vaginal	1 (1.6)	60 (98.4)	0.375	0	5 (100.0)	1.000
	caesarean section	1 (6.3)	15 (93.8)		1 (4.3)	22 (95.7)	
Any faecal leakage	vaginal	8 (13.1)	53 (86.9)	0.675	0	5 (100.0)	1.000
	caesarean section	1 (6.3)	15 (93.7)		1 (4.3)	22 (95.6)	

[↗] Fischer's exact test

Along with bowel function, one of the study objectives was to evaluate the association between mode of birth and anal sphincter muscles integrity on QoL following a subsequent birth for women with previous OASIS. Further analysis was undertaken on the data from the 105 women undergoing EAUS following the study birth to explore if the actual birth mode was a factor contributing to a worsening, no change or improvement in QoL scores for the women with a known sphincter defect or without any sphincter defect. The 105 women who underwent postnatal EAUS were dichotomised into two groups of either 'no sphincter abnormality' or 'extensive scarring or defect present'. A comparison of any changes in QoL as captured by the MHQ prior to and following the study birth depending of the mode of birth (either vaginal or caesarean section), was then performed for both of these groups (Table 4.45).

For the 28 women in the study who had an anal sphincter defect diagnosed on EAUS following the study birth, the mode of subsequent birth of either vaginal or caesarean section had no significant association for worsening, no change or improvement in any of the nine QOL domains (Table 4.45)

For the 77 women in the study who had no anal sphincter defect following the study birth, 'Physical Limitations' was the only QoL domain where there was an association and the mode of the study birth was of significance with those who had a caesarean section more likely to have an improved score (p=0.014) (Table 4.45).

Table 4.45 Comparison of changes in MHQ QoL scores prior to and following study birth for women with no sphincter abnormality or extensive scarring or defect by mode of study birth

		EAUS findings following subsequent study birth, N=105 (vaginal birth = 66, caesarean section = 39)							
		No sphincter abnormality, n=77, n (%)				Extensive scarring or defect present, n=28, n (%)			
		Postnatal MHQ QoL domain score compared to antenatal MHQ QoL domain score				Postnatal MHQ QoL domain score compared to antenatal MHQ QoL domain score			
MHQ QoL domain	Mode of study birth	Worsened score	No change in score	Improved score	*p* value[↗]	Worsened score	No change in score	Improved score	*p* value[↗]
General Health Perception (GHP)	vaginal	8 (13.1)	37 (60.7)	16 (23.2)	0.674	1 (20.0)	3 (60.0)	1 (20.0)	0.280
	caesarean section	2 (12.5)	8 (50.0)	6 (37.5)		0	14 (60.9)	9 (39.1)	
Incontinence Impact (II)	vaginal	11 (18.0)	38 (62.3)	12 (19.7)	1.000	1 (20.0)	4 (80.0)	0	0.335
	caesarean section	3(18.8)	10 (62.5)	3 (18.8)		2 (8.7)	14 (60.9)	7 (30.4)	
Role Limitations (RL)	vaginal	6 (9.9)	51 (83.6)	4 (6.6)	0.109	2 (40.0)	3 (60.0)	0	0.144
	caesarean section	4 (25.0)	10 (62.5)	2 (12.5)		1 (4.4)	19 (82.6)	3 (13.0)	
Physical Limitations (PL)	vaginal	1 (1.6)	53 (86.9)	7 (11.5)	*0.014*	1 (20.0)	4 (80.0)	0	1.000
	caesarean section	2 (12.5)	9 (56.3)	5 (31.2)		3 (13.0)	17 (73.9)	3 (13.0)	
Social Limitations (SL)	vaginal	2 (3.3)	55 (90.2)	4 (6.6)	0.400	1 (20.0)	4 (80.0)	0	0.658
	caesarean section	1 (6.25)	13 (81.3)	2 (12.5)		2 (8.7)	19 (82.6)	2 (8.7)	
Personal Relationships (PR)	vaginal	3 (4.9)	54 (88.5)	4 (6.6)	0.590	1 (20.0)	4 (80.0)	0	0.459
	caesarean section	1 (6.25)	11 (68.8)	4 (25.0)		1 (4.4)	21 91.3)	1 (4.4)	
Emotions (E)	vaginal	6 (9.9)	46 (75.4)	9 (14.8)	0.556	1 (20.0)	3 (60.0)	1 (20.0)	0.367
	caesarean section	0	13 (81.3)	3 (18.8)		2 (8.7)	18 (78.3)	3 (13.0)	
Sleep/Energy (SE)	vaginal	2 (3.3)	54 (88.5)	5 (8.2)	0.522	0	5 (100.0)	0	1.000
	caesarean section	1 (6.25)	13 (81.3)	2 (12.5)		2 (8.7)	19 (82.6)	2 (8.7)	
Severity Measure (SM)	vaginal	4 (6.6)	45 (73.8)	12 (19.7)	0.143	1 (20.0)	4 (80.0)	0	1.000
	caesarean section	2 (12.5)	8 (50.0)	6 (37.5)		4 (17.4)	15 (65.2)	4 (17.4)	

[↗] Fischer's exact test

4.11.9 Subsequent vaginal birth – repeat OASIS and perineal trauma

Recurrent OASIS rate and extent of perineal trauma for women undergoing a vaginal birth during the study were also investigated. For the 105 women who underwent a vaginal study birth, four (3.8%) sustained a repeat OASIS; two women had a 3a OASIS (one woman whose previous OASIS was a 3b classification and the other woman whose previous OASIS was classified as a 3c) and two sustained a 3b OASIS (one woman whose previous OASIS was a 3b classification and the other woman whose previous OASIS was classified as a 3c). An episiotomy/second degree perineal trauma was sustained in 71.4% (75/105) of the women undergoing a vaginal study birth and 14.3% (15/105) women had a labial/first degree perineal laceration. The remaining 10.5% (11/105) of the women were recorded as having no perineal trauma.

From the four women who sustained a repeat OASIS, three attended for their postnatal EAUS and also completed the MHQ; for the woman who sustained a 3a OASIS during the study birth there was no anal sphincter abnormalities seen on EAUS and the changes she reported were a worsening of faecal urgency, an improvement in flatus control and an improvement in the 'Severity Measure' QoL domain, one of the women who sustained a 3b OASIS during the study birth also had no anal sphincter abnormality seen on EAUS, however, she reported worsening of both faecal urgency and control of flatus and a worsening in six of the QoL domains, for the remaining woman who had a 3b OASIS during the study birth, despite extensive scarring or defect being seen on the postnatal EAUS the only change to her bowel function and QoL was an improvement in faecal urgency.

4.11.10 Multivariate analysis of antenatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on bowel function post study birth

To examine the relationship between antenatal bowel function prior to the study birth and bowel function following the study birth (faecal urgency, difficulty wiping clean, poor control of flatus and any faecal leakage) a multivariate logistic regression model was used with post study birth bowel function as the outcome and antenatal bowel function as covariates with adjustment for contributory maternal, intrapartum, OASIS and neonatal characteristics. This is shown in table 4.46. Due to the small numbers, for this analysis bowel symptoms of faecal urgency, poor control of flatus, difficulty wiping clean and any faecal leakage were dichotomised into being 'absent' or 'present'.

There was no independent association between the mode of study birth and any of the bowel symptoms at six months postpartum. There were, however, several characteristics that were independently associated with post-study birth bowel symptoms. Faecal urgency experienced prior to the study birth was significantly associated with faecal urgency following the study birth (OR 5.90, 95% CI 1.45-24.02). Difficulty wiping clean experienced prior to the study birth was significantly associated with difficulty wiping clean following the study birth (OR 18.15, 95% CI 5.44-60.59) and any faecal leakage following the study birth (OR 4.35, 95% CI 1.12-16.97). Poor control of flatus experienced prior to the study birth was a significantly associated with poor control of flatus following the study birth (OR 5.42, 95% CI 1.90-15.51). Both any faecal leakage (OR 13.60, 95% CI (3.17-58.32), and difficulty

wiping clean (OR 5.88, 95% CI 1.74-19.86) experienced prior to the study birth were significant associated with any faecal leakage following the study birth.

With regard to maternal characteristics, age when the OASIS was sustained was significantly associated with difficulty wiping clean following the study birth (OR 1.28, 95% CI 1.10-1.49). The odds of faecal urgency following the study birth were decreased for women with a total parity of three or more when compared to women with a total parity of two (OR 0.19, 95% CI 0.04-0.95). If the woman had undergone a vaginal interval birth(s) did not have a significant association with faecal urgency, difficulty wiping clean, poor control of flatus or any faecal leakage following the study birth.

Regarding characteristics of the birth in which OASIS was sustained, only the OASIS birth mode of forceps (any type) was significantly associated with faecal urgency following the study birth (OR 11.60, 95% CI 2.0-70.22) when compared to women who had sustained OASIS during a SVD. The odds of faecal urgency following the study birth were decreased for women with a 3C/4 OASIS when compared to women with a 3A OASIS classification (OR 0.03, 95% CI 0.00-0.28), whereas a 3B OASIS did not have a significant association with any of the four post study birth bowel symptoms. When compared against the reference OASIS repair method of 'end-to-end' technique, no repair method (either 'overlap' or 'unspecified') was found to have a significant association with faecal urgency, difficulty in wiping clean, poor control of flatus or any faecal leakage following the study birth.

The neonatal characteristic of birthweight for the study birth was not significantly associated with any of the bowel symptoms following the study birth.

Due to the low number of events, the results of this multivariate analysis need to be interpreted with caution as the confidence intervals are large and therefore precision of the estimates is low.

Table 4.46 Multivariate analysis of antenatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on bowel function post study birth

Characteristic (n/125)		Postnatal bowel symptoms: Faecal Urgency OR	95% CI	*p*	Difficulty wiping clean OR	95% CI	*p*	Poor control of flatus OR	95% CI	*p*	Any faecal leakage OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion													
Faecal urgency													
Absent	(28)		Reference			Reference			Reference			Reference	
Present	(97)	5.90	(1.45-24.02)	*0.013*	0.69	(0.15-3.07)	0.621	0.73	(0..23-2.33)	0.596	2.82	(0.47-17.06)	0.259
Difficulty wiping clean													
Absent	(73)		Reference			Reference			Reference			Reference	
Present	(52)	0.97	(0.27-3.54)	0.964	18.15	(5.44-60.59)	*<0.001*	2.14	(0.80-5.75)	0.131	5.88	(1.74-19.86)	*0.004*
Poor control of flatus													
Absent	(53)		Reference			Reference			Reference			Reference	
Present	(72)	2.22	(0.58-8.59)	0.246	1.09	(0.31-3.79)	0.895	5.42	(1.90-15.51)	*0.002*	0.31	(0.08-1.26)	0.102
Any faecal leakage													
Absent	(93)		Reference			Reference			Reference			Reference	
Present	(32)	7.90	(1.08-58.03)	*0.042*	4.35	(1.12-16.97)	*0.034*	3.22	(0.89-11.69)	0.076	13.60	(3.17-58.32)	*<0.001*
Maternal characteristics													
Age at OASIS		0.99	(0.87-1.13)	0.884	1.28	(1.10-1.49)	*0.001*	1.02	(0.92-1.14)	0.669	1.08	(0.94-1.24)	0.271
Vaginal interval birth(s)													
None	(103)		Reference			Reference			Reference			Reference	
≥ 1	(22)	0.76	(0.10-5.92)	0.791	2.76	(0.35-21.46)	0.333	0.85	(0.14-5.09)	0.859	1.04	(0.14-7.82)	0.968
Parity (all birth modes)													

2	(87)		Reference			Reference			Reference			Reference	
≥ 3	(38)	0.19	(0.04-0.95)	*0.043*	0.45	(0.09-2.24)	0.331	0.40	(0.10-1.65)	0.206	0.86	(0.17-4.42)	0.852
Mode of study birth													
Vaginal	(74)		Reference			Reference			Reference			Reference	
Caesarean section	(51)	0.43	(0.12-1.58)	0.200	1.15	(0.37-3.55)	0.809	0.82	(0.29-2.33)	0.712	0.78	(0.24-2.52)	0.675
Intrapartum characteristics													
OASIS birth mode													
SVD	(75)		Reference			Reference			Reference			Reference	
Kiwi	(16)	3.63	(0.50-26.60)	0.204	0.29	(0.05-1.57)	0.149	3.85	(0.94-15.78)	0.061	2.98	(0.54-15.78)	0.199
Any forceps	(34)	11.60	(2.00-70.22)	*0.006*	0.71	(0.20-2.54)	0.600	2.05	(0.65-6.47)	0.222	0.83	(0.21-3.28)	0.789
OASIS characteristics													
OASIS classification													
3A	(37)		Reference			Reference			Reference			Reference	
3B	(43)	0.26	(0.04-1.82)	0.175	0.59	(0.12-2.92)	0.517	1.87	(0.47-7.38)	0.374	1.60	(0.26-10.01)	0.613
3C/4	(19)	0.03	(0.00-0.28)	*0.003*	0.35	(0.05-2.30)	0.273	1.53	(0.30-7.76)	0.608	4.58	(0.62-33.72)	0.135
Unspecified	(26)	1.41e-07	(0)	0.988	1.05e-07	(0)	0.991	4.75e-07	(0)	0.994	2.30e+07	(0)	0.990
OASIS repair method													
End-to-end	(55)		Reference			Reference			Reference			Reference	
Overlap	(41)	3.95	(0.71-21.95)	0.117	0.46	(0.11-1.96)	0.295	0.69	(0.21-2.28)	0.546	0.76	(0.18-3.22)	0.707
Unspecified	(29)	2547505	(0)	0.988	3567655	(0)	0.992	1.11e+07	(0)	0.993	2.13e-07	(0)	0.991
Neonatal characteristics													
Birthweight (for study birth)		1.00	(1.00-1.00)	0.058	1.00	(1.00-1.00)	0.580	1.00	(1.00-1.00)	0.985	0.999	(1.00-1.00)	0.154

4.11.11 Multivariate analysis of antenatal bowel function and QoL scores, maternal, intrapartum, OASIS and neonatal characteristics on QoL scores post study birth

An aim of the study was to identify any significant independent characteristics that may contribute to QoL following the study birth. Table 4.47 shows the multivariate analysis investigating the association of antenatal bowel function prior to the study birth and maternal, intrapartum, OASIS and neonatal characteristics with the outcome of a negative impact (MHQ domain score of ≥ one) for each of the nine MHQ QoL domains at postnatal questionnaire completion. As with multivariate analysis undertaken for bowel function in section 4.10.10, due to the small numbers, for this analysis bowel symptoms of faecal urgency, poor control of flatus, difficulty wiping clean and any faecal leakage were dichotomised into being 'absent' or 'present'. For the QoL domains of 'Physical Limitations' and 'Social Limitations' the bowel symptom of faecal urgency was removed as a contributory characteristic due to the low number of events.

There was no independent association between the mode of study birth and an impact on any of the nine QoL domains as six months postpartum. There were, however, several of the characteristics that were independently associated with an impact on QoL. The odds of poor QoL following the study birth for the domain of 'Role Limitations' (OR 10.36; 95% CI 1.77-60.54) was significantly higher for women who had experienced faecal urgency prior to the study birth compared with women who did not have faecal urgency. The odds for poor QoL following the study birth for the domains of 'Physical Limitations' (OR 6.61; 95% CI 1.19-36.76), 'Social

Limitations' (OR 61.72, 95% CI 3.94-968.13) and 'Personal Relationships' (OR 32.53, 95% CI 2.02-523.31) were significantly higher for women who had any faecal leakage prior to the study birth when compare with women who did not. However, difficulty wiping clean and poor control of flatus experienced prior to the study birth did not have a significant association with any of the nine MHQ QoL domains.

The odds for a poor QoL were significantly higher for women who had a corresponding negative impact domain score (MHQ domain score ≥ one) prior to the study birth for the domains of 'General Health Perception' (OR 13.74; 95% CI 4.43-42.62), 'Incontinence Impact' (OR 14.88, 95% CI 4.42-50.10), 'Role Limitations' (OR 116.38, 95% CI 16.62-815.02), 'Physical Limitations' (OR 9.17, 95% CI 1.57-53.48), 'Social Limitations' (OR 46.33, 95% CI 2.21-971.03), 'Emotions' (OR 48.04, 95% CI 10.71-215.42), 'Sleep/Energy' (OR 21.29, 95% CI 2.99-151.54), 'Severity Measures' (OR 22.28, 95% CI 5.20-95.39) compared to women who had a no impact pre-study birth QoL score (MHQ domain score = zero).

When considering maternal characteristics in conjunction with QoL, the age at which the initial OASIS was sustained was found to be a significant independent predictor for a negative impact on the QoL domains of 'Social Limitations' (OR 1.52, 95% CI 1.04-2.22), and 'Personal Relationships' (OR 1.59, 95% CI 1.11-2.27). The odds for a poor QoL for the domains of General Health Perception' (OR 6.73, 95% CI 1.07-42.53), and 'Role Limitations' (OR 154.96, 95% CI 1.73-13865.45) were significantly higher for women who had experienced a vaginal interval birth(s) when compared to women who had not. With regard to parity, a total parity of three or more in

comparison to a parity of two did not have a significant positive or negative association with any of the nine QoL domains.

For mode of the birth during which OASIS was sustained, when compared to the reference of a spontaneous vaginal birth, the comparator characteristics of kiwi or any forceps did not have a significant positive or negative association with any of the nine QoL domains.

Interestingly, the odds for an improved QoL for the domain of 'Incontinence Impact' (OR 0.15; 95% CI 0.03-0.75) was significantly higher for women who had a 3C/4 when compared to the reference OASIS classification of 3A. Whereas the odds for a poor QoL for the domain of 'Role Limitations' (R 187.18, 95% CI 2.59-13551.34) was significantly higher for women with an unspecified OASIS when compared to the reference OASIS classification of 3A. For the method of OASIS repair, the odds for an improved QoL for the domain of 'Role Limitations' (OR 0.05, 95% CI 0.00-0.17) was significantly higher for women whose repair method was unknown ('unspecified'), when compared to the 'end-to-end' repair method.

The characteristic of neonatal birthweight for the study birth was not found to have significant positive or negative association with any of the nine QoL domains.

Due to the low number of events, the results of this multivariate analysis need to be interpreted with caution as the confidence intervals are large and therefore precision of the estimates is low.

Table 4.47 Multivariate analysis of antenatal bowel function and QoL scores, maternal, intrapartum, OASIS and neonatal characteristics on QoL scores post study birth

Characteristic (n/125)		Postnatal MHQ QoL domains: General Health Perception OR	95% CI	*p*	Incontinence Impact OR	95% CI	*p*	Role Limitations OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion										
Faecal urgency										
Absent	(28)		Reference			Reference			Reference	
Present	(97)	0.73	(0.22-2.48)	0.618	0.71	(0.20-2.43)	0.580	10.36	(1.77-60.54)	*0.009*
Difficulty wiping clean										
Absent	(73)		Reference			Reference			Reference	
Present	(52)	0.71	(0.28-1.85)	0.486	2.10	(0.76-5.84)	0.154	0.46	(0.08-2.53)	0.368
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(72)	0.73	(0.25-2.14)	0.571	0.88	(0.30-2.65)	0.825	1.42	(0.23-8.89)	0.705
Any faecal leakage										
Absent	(93)		Reference			Reference			Reference	
Present	(32)	1.21	(0.41-3.57)	0.726	1.56	(0.47-5.24)	0.468	1.57	(0.20-12.29)	0.670
Corresponding antenatal MHQ domain score										
No impact on QoL (score=0)			Reference			Reference			Reference	
Negative impact on QoL (score ≥ 1)		13.74	(4.43-42.62)	*<0.001*	14.88	(4.42-50.10)	*<0.001*	116.38	(16.62-815.02)	*<0.001*
Maternal characteristics										
Age at OASIS		0.98	(0.88-1.09)	0.693	1.01	(0.91-1.13)	0.818	1.07	(0.91-1.26)	0.404

Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
≥ 1	(22)	6.73	(1.07-42.53)	*0.043*	0.67	(0.11-4.20)	0.671	154.96	(1.73-13865.45)	*0.028*
Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(38)	0.40	(0.09-1.75)	0.225	1.35	(0.31-5.89)	0.689	0.19	(0.02-1.60)	0.127
Mode of study birth										
Vaginal	(74)		Reference			Reference			Reference	
Caesarean section	(51)	1.04	(0.39-2.76)	0.935	0.90	(0.30-2.73)	0.855	0.42	(0.09-1.90)	0.258
Intrapartum characteristics										
OASIS birth mode										
SVD	(75)		Reference			Reference			Reference	
Kiwi	(16)	0.87	(0.22-3.47)	0.845	1.38	(0.34-5.55)	0.649	3.78	(0.36-39.71)	0.268
Any forceps	(34)	0.87	(0.30-2.54)	0.795	0.70	(0.22-2.26)	0.552	1.64	(0.29-9.40)	0.580
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	1.07	(0.30-3.90)	0.915	0.37	(0.09-1.56)	0.175	1.30	(0.12-14.73)	0.830
3C/4	(19)	1.13	(0.26-4.90)	0.875	0.15	(0.03-0.75)	*0.020*	0.29	(0.02-4.04)	0.354
Unspecified	(26)	0.10	(0.00-2.25)	0.145	0.75	(0.03-17.30	0.855	187.18	(2.59-13551.34)	*0.017*
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	1.87	(0.57-6.17)	0.300	3.60	(0.99-13.17)	0.053	0.97	(0.13-7.21)	0.979
Unspecified	(29)	9.51	(0.44-206.45)	0.151	0.84	(0.04-16.82)	0.908	0.00	(0.00-0.17)	*0.005*
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.186	1.00	(1.00-1.00)	0.892	1.00	(1.00-1.00)	0.212

Characteristic (n/125)		Physical Limitations			Social Limitations			Personal Relationships		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion										
Faecal urgency										
Absent	(28)	----	----	----	----	----	----		Reference	
Present	(97)	----	----	----	----	-----	----	4.30	(0.16-114.67)	0.384
Difficulty wiping clean										
Absent	(73)		Reference			Reference			Reference	
Present	(52)	2.04	(0.44-9.43)	0.363	4.35	(0.59-31.86)	0.148	0.26	(0.02-3.44)	0.309
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(72)	1.20	(0.21-7.04)	0.839	0.57	(0.04-8.48)	0.681	0.20	(0.02-1.91)	0.163
Any faecal leakage										
Absent	(93)		Reference			Reference			Reference	
Present	(32)	6.61	(1.19-36.76)	*0.031*	61.72	(3.94-968.13)	*0.003*	32.53	(2.02-523.31)	*0.014*
Corresponding antenatal MHQ domain score										
No impact on QoL (score=0)			Reference			Reference			Reference	
A negative impact on QoL (score ≥ 1)		9.17	(1.57-53.48)	*0.014*	46.33	(2.21-971.03)	*0.013*	17.30	(0.70-427.73)	0.082
Maternal characteristics										
Age at OASIS		1.20	(0.98-1.46)	0.079	1.52	(1.04-2.22)	*0.030*	1.59	(1.11-2.27)	*0.011*
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
Vaginal	(22)	3.78	(0.29-49.04)	0.310	8.39	(0.19-369.29)	0.271	0.97	(0.02-57.20)	0.987
Total Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(38)	1.21	(0.16-9.25)	0.857	0.82	(0.06-11.83)	0.887	2.19	(0.08-58.04)	0.640

Mode of study birth										
Vaginal	(74)		Reference			Reference			Reference	
Caesarean section	(51)	3.96	(0.84-18.77)	0.083	4.53	(0.46-44.43)	0.194	0.30	(0.03-2.84)	0.292
Intrapartum characteristics										
OASIS birth mode										
SVD	(75)		Reference			Reference			Reference	
Kiwi/ventouse	(16)	3.83	(0.52-28.35)	0.188	0.11	(0.00-6.10)	0.280	0.11	(0.00-6.70)	0.291
Any forceps	(34)	0.95	(0.18-5.13)	0.956	0.20	(0.02-2.33)	0.197	0.34	(0.03-3.92)	0.388
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	4.67	(0.42-51.94)	0.210	0.07	(0.00-2.49)	0.144	2.14	(0.15-29.66)	0.570
3C/4	(19)	0.96	(0.07-13.10)	0.974	0.11	(0.00-3.08)	0.194	2.09	(0.10-44.95)	0.637
Unspecified	(26)	1.93	(0.09-43.02)	0.679	2.10e+08	(0)	0.996	0.03	(0.00-2.60)	0.126
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	2.07	(0.26-16.74)	0.495	19.60	(0.87-440.57)	0.061	0.23	(0.02-2.63)	0.238
Unspecified	(29)	3.31	(0.15-73.81)	0.450	6.70e-09	(0)	0.996	9.42	(0.27-324.06)	0.214
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.270	1.00	(1.00-1.00)	0.746	1.00	(1.00-1.00)	0.964

Characteristic (n/125)		**Emotions**			**Sleep/Energy**			**Severity Measures**		
		OR	95% CI	*P*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion										
Faecal urgency										
Absent	(28)		Reference			Reference			Reference	
Present	(97)	0.89	(0.19-4.18)	0.886	0.36	(0.03-4.46)	0.429	0.39	(0.08-1.92)	0.245

Difficulty wiping clean										
Absent	(73)		Reference			Reference			Reference	
Present	(52)	1.66	(0.50-5.48)	0.405	0.93	(0.15-5.78)	0.940	1.35	(0.40-4.60)	0.634
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(72)	0.47	(0.11-1.97)	0.302	1.68	(0.16-18.28)	0.669	1.25	(0.34-4.66)	0.739
Any faecal leakage										
Absent	(93)		Reference			Reference			Reference	
Present	(32)	1.21	(0.29-5.08)	0.792	3.79	(0.64-22.45)	0.142	4.18	(0.99-17.42)	0.052
Corresponding antenatal MHQ domain score										
No impact on QoL (score=0)			Reference			Reference			Reference	
A negative impact on QoL (score ≥ 1)		48.04	(10.71-215.42)	*<0.001*	21.29	(2.99-151.54)	*0.002*	22.28	(5.20-95.39)	*<0.001*
Maternal characteristics										
Age at OASIS		1.10	(0.95-1.26)	0.196	1.03	(0.83-1.26)	0.818	1.07	(0.94-1.23)	0.305
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
Vaginal	(22)	1.32	(0.16-10.62)	0.793	0.61	(0.04-10.40)	0.735	0.26	(0.03-2.52)	0.247
Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(38)	3.36	(0.63-17.85)	0.155	6.99	(0.78-62.95)	0.083	1.60	(0.29-8.83)	0.588
Mode of study birth										
Vaginal	(74)		Reference			Reference			Reference	
Caesarean section	(51)	0.94	(0.28-3.19)	0.924	3.91	(0.54-28.01)	0.175	1.08	(0.32-3.65)	0.900
Intrapartum characteristics										
OASIS birth mode										
SVD	(75)		Reference			Reference			Reference	

Kiwi	(16)	2.26	(0.42-12.24)	0.345	0.47	(0.03-6.38)	0.569	2.16	(0.42-11.20)	0.357
Any forceps	(34)	1.06	(0.25-4.52)	0.941	0.88	(0.13-5.73)	0.889	0.25	(0.06-1.17)	0.079
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	1.13	(0.21-6.10)	0.890	0.58	(0.05-7.31)	0.672	2.64	(0.49-15.57)	0.283
3C/4	(19)	1.23	(0.20-7.49)	0.821	0.23	(0.01-4.58)	0.336	2.46	(0.39-15.56)	0.340
Unspecified	(26)	8.32	(0.29-235.21)	0.214	1037799	(0)	0.995	0.06	(0.00-2.54)	0.142
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	1.33	(0.30-5.83)	0.710	1.13	(0.13-10.00)	0.915	0.71	(0.16-3.05)	0.640
Unspecified	(29)	0.07	(0.00-1.64)	0.097	9.60e-07	(0)	0.995	12.44	(0.36-426.34)	0.162
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.759	1.00	(1.00-1.00)	0.370	1.00	(1.00-1.00)	0.560

4.11.12 Multivariate analysis of postnatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on QoL scores post study birth

As well as investigating antenatal (pre-study birth) bowel symptoms as possible contributory characteristics for postnatal (post-study birth) QoL (section 4.10.11), the effect of postnatal bowel symptoms was also investigated. A multivariate analysis of bowel function following the study birth and maternal, intrapartum, OASIS and neonatal characteristics with the outcome of a negative impact (MHQ domain score of ≥ one) for each of the nine MHQ QoL domains at postnatal questionnaire completion, was also performed (Table 4.48). For the QoL domains of 'Physical Limitations', 'Social Limitations' and 'Personal Relationships' the bowel symptom of faecal urgency was removed as a contributory characteristic due to the low number of events.

The odds of poor QoL for the domains of 'Incontinence Impact' (OR 2.91, 95% CI 1.03-8.21) and 'Physical Limitations' (OR 4.56, 95% CI 1.02-20.45) were significantly higher for women who had their study birth by caesarean section when compared to those who had a vaginal study birth. However, the mode of study birth was was not found to have significant positive or negative association with any of the other seven MHQ QoL domains.

The odds of poor QoL for the domains of 'Role Limitations' (OR 5.10; 95% CI 1.32-19.75) and 'Sleep/Energy' (OR 16.16, 95% CI 1.14-228.62) were significantly higher in women who had faecal urgency following the study birth when compared to women who did not have this symptom. The odds of poor QoL for the domains of

'Incontinence Impact' (OR 6.44, 95% CI 2.13-19.53), 'Physical Limitations' (OR 4.95, 95% CI 1.22-20.11), 'Emotions' (OR 3.89, 95% CI 1.40-10.78) and 'Severity Measure' (OR 5.40, 95% CI 1.71-17.02) were significantly higher for women who had difficulty wiping clean following the study birth when compared to women who did not experience this. However, the odds for an improved QoL for the domain of 'General Health Perception' (0.33, 95% CI 0.12-0.87) was significantly increased for women with difficulty wiping clean when compared to women who did not experience this. The odds of poor QoL for the domain of 'Incontinence Impact' (OR 5.07, 95% CI 1.65-15.58) was significantly increased for women who had poor control of flatus following the study birth when compared to women who had good flatal control. The odds of poor QoL for the domains of 'Social Limitations' (OR 9.49, 95% CI 1.73-52.03), 'Sleep/Energy' (OR 5.21, 95% CI 1.04-26.23) and 'Severity Measures' (OR 5.54, 95% CI 1.63-18.77) were significantly increased for women who had any faecal leakage following the study birth when compared to women who did not.

When considering maternal characteristics in conjunction with postnatal bowel symptoms, the odds of poor QoL for the domain of 'Emotions' (OR 8.49, 95% CI 0.79-6.11) was significantly increased for women with a parity of three or more when compared to women with a parity of two.

For mode of the birth during which OASIS was sustained the odds of poor QoL for the domain of 'Severity Measure' (OR 0.24, 95% CI 0.06-0.96) were significantly increased for women who had a birth assisted with 'any forceps' when compared to the reference characteristic of a spontaneous vaginal birth, whereas the OASIS birth

mode of ‘kiwi’ was not found to have significant negative or positive associations with any of the nine MHQ QoL domains.

When compared to the reference OASIS classification of 3A, the odds of poor QoL for the QoL domain of ‘Incontinence Impact’ (OR 0.17; 95% CI 0.03-0.98) were significantly increased for women who had a 3C/4 OASIS. However, a 3B or ‘unspecified’ OASIS were both not found to have significant negative or positive associations with any of the nine MHQ QoL domains. For the method of OASIS repair, when compared to ‘end-to-end’, the odds of poor QoL for the domain of ‘Incontinence Impact’ (OR4.23, 95% CI 1.14-15.77) were significantly increased for women who had an ‘overlap’ repair. However, an ‘unspecified’ repair was not found to have significant negative or positive associations with any of the nine MHQ QoL domains.

The characteristics of age when the OASIS was sustained, neonatal birthweight for the study birth and having a vaginal interval birth(s) in comparison to not having had one were not found to have significant negative or positive associations with any of the nine MHQ QoL domains.

Due to the low number of events, the results of this multivariate analysis need to be interpreted with caution as the confidence intervals are large and therefore precision of the estimates is low.

Table 4.48 Multivariate analysis of postnatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on QoL scores post study birth

Characteristic (n/125)		Postnatal MHQ QoL domains: General Health Perception OR	95% CI	*p*	Incontinence Impact OR	95% CI	*p*	Role Limitations OR	95% CI	*p*
Bowel symptoms at postnatal MHQ completion										
Faecal urgency										
Absent	(28)		Reference			Reference			Reference	
Present	(97)	2.38	(0.80-7.14)	0.121	0.93	(0.26-3.32)	0.912	5.10	(1.32-19.75)	*0.018*
Difficulty wiping clean										
Absent	(73)		Reference			Reference			Reference	
Present	(52)	0.33	(0.12-0.87)	*0.025*	6.44	(2.13-19.53)	*0.001*	0.43	(0.13-1.51)	0.189
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(72)	0.83	(0.31-2.16)	0.703	5.07	(1.65-15.58)	*0.005*	1.22	(0.37-4.07)	0.743
Any faecal leakage										
Absent	(93)		Reference			Reference			Reference	
Present	(32)	1.90	(0.68-5.28)	0.220	1.83	(0.58-5.69)	0.301	3.01	(0.55-16.54)	0.206
Maternal characteristics										
Age at OASIS		1.00	(0.91-1.10)	0.923	0.91	(0.82-1.02)	0.107	1.12	(0.98-1.28)	0.094
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
≥ 1	(22)	3.71	(0.77-17.81)	0.102	0.40	(0.07-2.40)	0.316	15.80	(1.01-247.21)	*0.049*

Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(38)	0.83	(0.23-2.90)	0.765	5.12	(1.10-23.97)	*0.038*	0.81	(1.19-3.49)	0.782
Mode of study birth										
Vaginal	(74)		Reference			Reference			Reference	
Caesarean section	(51)	1.42	(0.61-3.30)	0.418	2.91	(1.03-8.21)	*0.044*	0.84	(0.28-2.48)	0.749
Intrapartum characteristics										
OASIS birth mode										
SVD	(75)		Reference			Reference			Reference	
Kiwi	(16)	0.45	(0.12-1.62)	0.219	1.75	(0.42-7.25)	0.443	0.80	(0.16-3.92)	0.778
Any forceps	(34)	0.51	(0.19-1.36)	0.177	0.60	(0.19-1.93)	0.394	0.45	(0.12-1.68)	0.234
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	0.90	(0.28-2.90)	0.859	0.29	(0.07-118)	0.084	2.89	(0.61-13.63)	0.179
3C/4	(19)	1.00	(0.24-4.17)	0.997	0.17	(0.03-0.98)	*0.047*	2.16	(0.34-13.68)	0.413
Unspecified	(26)	0.14	(0.01-2.30)	0.168	0.40	(0.02-9.81)	0.577	18.31	(0.55-615.99)	0.105
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	0.76	(0.27-2.12)	0.602	4.23	(1.14-15.77)	*0.032*	0.87	(0.22-3.48)	0.846
Unspecified	(29)	3.86	(0.27-55.25)	0.320	0.83	(0.04-17.10)	0.904	0.08	(0.00-3.12)	0.131
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.371	1.00	(1.00-1.00)	0.745	1.00	(1.00-1.00)	0.626

Characteristic (n/125)	**Physical Limitations**			**Social Limitations**			**Personal Relationships**		
	OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at postnatal MHQ completion									

Faecal urgency										
Absent	(28)	----	----	----	----	----	----	----	----	----
Present	(97)	----	----	----	----	-----	----	----	-----	----
Difficulty wiping clean										
Absent	(73)		Reference			Reference			Reference	
Present	(52)	4.95	(1.22-20.11)	*0.025*	3.12	(0.52-18.79)	0.215	3.89	(0.56-27.10)	0.170
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(72)	6.11	(0.88-42.53)	0.068	3.00	(0.41-21.80)	0.277	5.98	(0.63-57.03)	0.120
Any faecal leakage										
Absent	(93)		Reference			Reference			Reference	
Present	(32)	2.50	(0.64-9.68)	0.187	9.49	(1.73-52.03)	*0.010*	3.22	(0.54-19.19)	0.199
Maternal characteristics										
Age at OASIS		1.00	(0.85-1.17)	0.997	1.00	(0.82-1.23)	0.951	1.22	(0.98-1.52)	0.075
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
Vaginal	(22)	3.57	(0.26-48.11)	0.338	7.33	(0.33-163.94)	0.209	0.72	(0.04-14.21)	0.830
Total Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(38)	2.91	(0.46-18.42)	0.258	2.76	(0.30-25.69)	0.373	11.75	(1.00-138.06)	0.050
Mode of study birth										
Vaginal	(74)		Reference			Reference			Reference	
Caesarean section	(51)	4.56	(1.02-20.45)	*0.048*	7.37	(0.89-61.18)	0.064	0.90	(0.14-5.61)	0.908
Intrapartum characteristics										
OASIS birth mode										
SVD	(75)		Reference			Reference			Reference	
Kiwi/ventouse	(16)	3.30	(0.48-22.63)	0.224	0.31	(0.02-5.86)	0.433	0.72	(0.05-11.05)	0.814
Any forceps	(34)	0.54	(.012-2.45)	0.425	0.24	(0.03-2.09)	0.195	0.17	(0.02-1.37)	0.096

OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	8.27	(0.96-71.29)	0.054	0.42	(0.04-4.49)	0.471	4.09	(0.36-46.48)	0.256
3C/4	(19)	1.00	(0.10-9.96)	1.000	0.08	(0.00-1.79)	0.110	0.27	(0.01-5.32)	0.393
Unspecified	(26)	0.83	(0.04-18.26)	0.905	807413.8	(0)	0.995			
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	0.87	(0.17-4.49)	0.863	4.02	(0.44-36.99)	0.220	0.17	(0.02-1.84)	0.144
Unspecified	(29)	3.32	(0.17-64.71)	0.429	6.42E-07	(0)	0.995	3.97	(0.14-109.96)	0.415
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.307	1.00	(1.00-1.00)	0.408	1.00	(1.00-1.00)	0.310

Characteristic (n/125)		**Emotions**			**Sleep/Energy**			**Severity Measures**		
		OR	95% CI	*P*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at postnatal MHQ completion										
Faecal urgency										
Absent	(28)		Reference			Reference			Reference	
Present	(97)	3.56	(0.86-14.68)	0.079	16.16	(1.14-228.62)	*0.040*	2.36	(0.44-12.66)	0.317
Difficulty wiping clean										
Absent	(73)		Reference			Reference			Reference	
Present	(52)	3.89	(1.40-10.78)	*0.009*	0.98	(0.19-5.02)	0.979	5.40	(1.71-17.02)	*0.004*
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(72)	2.09	(0.66-6.60)	0.210	0.60	(0.10-3.60)	0.572	1.88	(0.53-6.68)	0.331
Any faecal leakage										
Absent	(93)		Reference			Reference			Reference	

Present	(32)	1.56	(5.01-4.87)	0.443	5.21	(1.04-26.23)	*0.045*	5.54	(1.63-18.77)	*0.006*
Maternal characteristics										
Age at OASIS		1.01	(0.90-1.13)	0.851	0.97	(0.81-1.16)	0.707	0.94	(0.82-1.07)	0.320
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
Vaginal	(22)	0.56	(0.10-3.34)	0.527	1.17	(0.10-13.32)	0.901	0.42	(0.05-3.60)	0.427
Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(38)	8.49	(1.87-38.44)	*0.006*	5.72	(0.91-36.16)	0.064	3.45	(0.71-16.85)	0.126
Mode of study birth										
Vaginal	(74)		Reference			Reference			Reference	
Caesarean section	(51)	2.20	(0.79-6.11)	0.131	4.77	(0.90-25.17)	0.066	2.18	(0.69-6.82)	0.182
Intrapartum characteristics										
OASIS birth mode										
SVD	(75)		Reference			Reference			Reference	
Kiwi	(16)	1.13	(0.28-4.58)	0.866	0.29	(0.02-3.87)	0.346	1.28	(0.27-6.19)	0.755
Any forceps	(34)	0.36	(0.11-1.19)	0.094	0.46	(0.08-2.62)	0.383	0.24	(0.06-0.96)	*0.043*
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	1.25	(0.31-5.09)	0.753	1.31	(0.14-12.34)	0.816	3.63	(0.74-17.71)	0.111
3C/4	(19)	1.75	(0.34-9.11)	0.504	0.83	(0.04-15.52)	0.898	3.82	(0.57-25.52)	0.166
Unspecified	(26)	2.00	(0.11-36.11	0.640	2009844	(0)	0.993	0.11	(0.00-2.77)	0.179
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	0.90	(0.26-3.13)	0.863	0.47	(0.07-3.34)	0.451	0.40	(0.10-1.57)	0.188
Unspecified	(29)	0.30	(0.02-4.60)	0.384	1.80E-06	(0)	0.993	4.04	(0.20-81.98)	0.363
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.732	1.00	(1.00-1.00)	0.875	1.00	(1.00-1.00)	0.829

4.11.13 Analysis of data for women sustaining OASIS following introduction of RCOG Green-top Guidelines

As discussed in section 1.4 in July 2001 the RCOG published the first evidence based guidelines for structured recognition and repair of OASIS (15). The local clinical guidelines for repair of OASIS at the NHS Trust in which the study was undertaken were updated to incorporate these RCOG recommendations immediately following publication. Monthly audits are undertaken in the Trust for all local guidelines to ensure compliance and adhere to national clinical negligence legislation. Consequently data from women in the study who sustained OASIS prior to the introduction of the RCOG green top guideline may not be representative of those whose OASIS was identified and repaired following implantation of these recommendations. Therefore, in order to allow time for the RCOG Green-top Guideline evidence based recommendations to be embedded into clinical practice within the NHS Trust in which the study was undertaken, sensitivity analyses were conducted removing any women who sustained OASIS prior to January 2002. This was undertaken to see if there was a difference in predictor characteristics for bowel symptoms and an effect on QoL once OASIS repair was undertaken using the best practice technique.

There were 122 women (97.6%) who sustained OASIS after January 2002. Multivariate analyses as undertaken in sections 4.10.10, 4.10.11 and 4.10.12 were repeated and the pattern of associations were similar (see appendices 4.7, 4.8 and 4.9).

4.12 Discussion

The systematic review undertaken in chapter two, investigating the impact of a subsequent birth and its mode for women with previous OASIS, clearly demonstrated that the published studies available providing data suitable for inclusion in the systematic review displayed heterogeneity in study design, methodology and primary aim. Therefore, in order to enable more meaningful comparisons, the study findings will be compared to those of other published studies that were undertaken with similar study methodology and that also had comparable antenatal and/or postnatal assessment time periods (44, 64, 84, 88, 91, 92, 94, 99).

With regard to the incidence of bowel symptoms six months following the study birth, just over three quarters of the women (76.8%) had bowel urgency, just over half of the women (56.0%) had poor control of flatus and just over a third of women (34.4%) experienced difficulty in wiping clean. Just under a quarter of the women (23.2 %) had any faecal leakage and all reported faecal leakage was of loose stools with no women ever experiencing any leakage of solid stools. Scheer et al (2009) (44) found a slightly lower incidence of bowel urgency (65.9%) but a comparable incidence of poor control of flatus (59.1%). As previously discussed this may be attributable to a much smaller sample size of only 44 women as they used the same validated MHQ to capture the symptom incidence. However, Bondili et al (2011) (88) reported an incidence of faecal urgency in only 4.2% of women (11/260) and this marked lower incidence could be from the use of alternative bowel symptom questionnaires to capture the data that makes comparison of symptoms difficult and possible self-selection bias. There were other studies that reported incidences of AI for women

with previous OASIS following a subsequent birth at a comparable follow-up time point, however, due to reporting methodologies they did not separate individual bowel symptoms and therefore comparison of their incidence of each bowel symptom with that found in this study was not possible (84, 91, 92, 94, 99).

Given that, due to differences in the measurement and reporting systems used within the published studies, comparison of the incidence of bowel symptoms in women with previous OASIS both prior to and following a subsequent birth is challenging. Therefore, measuring the change in incidence is probably a better and, indeed, more useful measure of the impact of the subsequent birth on bowel function. In this study just over a third of the women in our study chose to pursue an elective caesarean for their subsequent birth due to the fear of worsening of existing bowel symptoms. Scheer et al (2009) also reported that the worry of developing new symptoms of AI after a subsequent birth as being the main concern of women with a previous OASIS when considering mode of a subsequent birth (44). With regard to the change (worsening, no change or improvement) of bowel symptoms, for the majority of women in this study the frequency of bowel symptoms following the study birth, irrespective of mode, remained the same. Interestingly, for each of the bowel symptoms, except leakage during sexual intercourse, a greater proportion of women had an improvement in bowel symptoms at six month following the study birth in comparison to the proportion of women who had a worsening.

With regard to the mode of the subsequent birth, there was no significant association between the mode of study birth and the presence or a change in bowel symptom

severity for any of the bowel symptoms, following the study birth. Scheer et al (2009) (44) also found improvements in bowel symptoms for women with previous OASIS following a subsequent birth. In their study the 35 women who underwent a recommended subsequent vaginal birth had improvements in faecal urgency, flatus incontinence and liquid faecal incontinence and the 9 women who underwent a recommended caesarean section reported improvements in faecal urgency and flatus incontinence. Such improvements in bowel function could be due to physiological changes that occur following the birth during the postnatal period when hormones and consequent bowel physiology are beginning to return to a pre-pregnancy state. This contrasts to findings from Reid et al (81), who found that more women who had a subsequent birth by caesarean section had AI at three year follow up than those who had a subsequent vaginal birth following OASIS (p=0.012). They proposed that this was due to the fact that women in their study were recommended a caesarean section if they had bowel symptoms and an increase in the proportion of these women was attributed to a worsening of pre-existing symptoms. However, the same recommendations were used for women in this study, and therefore it could be argued that improvement in bowel symptom may be influenced by achieving desired mode of birth, learning to cope with/adapt to symptoms of bowel symptoms in the longer term or actual improvement because of management interventions like dietary changes or physiotherapy; an association and rationale that was also found and suggested by Bondili et al (2011) (88). Fitzpatrick et al (2016) found no significant change in the continence score for the 139 women in their study who underwent a subsequent vaginal birth (0.9% vs 1.3%; p value not given) (94). Similarly, Karmarker et al (2014) found no change in the bowel symptoms for the 45

women in their study who underwent their planned subsequent births but they did report a worsening of bowel symptoms for three symptomatic women who did not get their planned elective caesarean (93). Harkin et al (2003) (84) found no change in bowel symptoms for the 95% of the women undergoing a subsequent birth (38/40) and a worsening of symptoms for the remaining 5% of women (2/40).

There was also no significant association between the mode of study birth, either vaginal or caesarean section, and a negative impact on QoL following the study birth for the women in this study. This finding was present when incorporating the mode of study birth as a characteristic within the multi-variate analyses and also as a single characteristic within uni-variate analysis when comparing mean MHQ QoL domain scores prior to and following the study birth. As demonstrated in the systematic review in chapter two, despite QoL being an important indicator for women with previous OASIS when deciding on future pregnancy and mode, research into this area is limited and there are only ten studies that have investigated long-term QoL for women with a previous OASIS. However, within those published studies only one study has investigated the association of mode of the subsequent birth with QoL. Contrary to findings from this study, Sheer et al (2009), through a sub-analysis of data from 44 women undergoing the recommended mode of subsequent birth, found a significant negative impact on QoL, for women having a recommended caesarean section versus a recommended vaginal birth (44). The authors suggest that the negative impact on QoL for the women having a recommended caesarean section could be attributed to a continuation of bowel symptoms that were present prior to the birth. Also, as previously discussed this may be attributable a much

smaller sample size of only 44 women as they used the same validated MHQ to capture QoL.

This study has also identified, through multivariate logistic regression modelling, the antenatal bowel symptoms, maternal, intrapartum, OASIS and neonatal characteristics that were significantly associated with bowel symptoms and QoL following the study birth. Whilst other studies have undertaken an initial assessment of bowel symptoms in women with previous OASIS prior to a subsequent birth the majority have not used this data to investigate whether these antenatal symptoms were characteristics associated with post subsequent birth bowel symptoms, but rather as a measure of change in incidence or comparison with women who did not sustain an OASIS. However, there is one study that did identify antenatal bowel symptoms for women with a previous OASIS that are associated with postnatal symptoms. In a study undertaken to investigate the impact of a subsequent birth on women with previous OASIS, An et al (2014), found in their sample of 67 women that low AI measurement scores pre-subsequent birth were a significant predictor of normal continence post-subsequent birth ($p=0.0002$). However, the authors did not specify the time point at which the postnatal review was undertaken.

This study found that an older maternal age at OASIS was significantly associated with the bowel symptom of difficulty wiping clean and a negative association with two MHQ QoL domains following the study birth. Systematic searches of the literature show there is no other study that has investigated maternal age as a possible contributory factor to bowel symptoms and QoL for women with previous OASIS following a subsequent birth and this finding could be due to an overall increase in

age when presenting during the subsequent pregnancy and associated age-related deterioration of the pelvic floor function. A total parity of three or more and if the woman had experienced a vaginal birth following the OASIS and prior to the study birth were both significant independent predictors for a negative impact on QoL. Again, systematic searches show there is no other study that has investigated this and this finding could be due to the associated stress and tiredness from mothering a larger family. An OASIS birth mode of any forceps and an OASIS classification of 3C/4 were both significant independent predictors of bowel symptoms and a negative impact on QoL following the study birth. Although, there has not been another study that has investigated this as a possible contributory factor, literature does provide evidence that forceps and OASIS tears of 3C/4 that involve the internal anal sphincter are both significant risk characteristics for ongoing bowel symptoms. Repair of the OASIS by overlap technique was found to be a significant independent predictor for a negative impact on QoL following the study birth. However, there has not been another study that has investigated this as a contributory factor for either bowel symptoms or a negative impact on QoL following a subsequent birth.

This study also explored if the presence or absence of an anal sphincter abnormality (excessive scarring or sphincter defect), following the study birth were significantly associated with postnatal bowel symptoms or a negative impact on QoL. Study findings showed that the presence of an anal sphincter abnormality following the study birth, irrespective of mode of birth, was not significantly associated with the presence or worsening of any bowel symptom or a negative impact or worsening of on any of the nine MHQ QoL domains. Also, when this analysis was repeated with

mode of study birth as the comparator characteristic, the presence of an anal sphincter abnormality following the study birth was still not significantly associated with a worsening of any bowel symptom. The mode of study birth was only of significance for changes in one QoL domain for women who had no anal sphincter abnormality. These findings are interesting as anal sphincter abnormalities are a known cause of bowel symptoms. These findings could be a demonstration that, even during the postnatal period when hormonal changes can impact negatively on bowel function, physiologically maternal age is affording a compensatory mechanism. Also, mode of birth may not have been found to be significantly associated with the presence of post study birth bowel symptoms as women who had known anal abnormalities and/or bowel symptoms were offered an elective caesarean section in line with the current RCOG guidelines.

4.12.1 Strengths and limitations

This study has several strengths. Of the few studies undertaken to investigate the impact of a subsequent birth this study has the largest consecutively recruited sample size. Follow-up response was high, at 71.4%, but as with all cohort studies that include a follow-up assessment even relatively low attrition needs to be considered. Baseline comparison of the responders and non-responders at follow-up was therefore undertaken to investigate potential for bias. Comparison of the baseline characteristics, antenatal bowel function and antenatal QoL of the responders and non-responders to the postnatal MHQ showed few differences. With regard to baseline characteristics method of repair and birthweight were the only two characteristics that were significantly different between the women who

completed the postnatal MHQ and those that did not. These characteristics are likely to be chance findings. Comparison of antenatal bowel symptoms showed the only significant difference was with poor control of flatus with more women who completed the postnatal MHQ having poor control at the time of antenatal MHQ completion. Comparison of antenatal MHQ QoL scores only the domain of 'Emotions' showed a significant difference with more women who completed the postnatal MHQ having a score that resulted in a negative impact on this domain. These findings reduce the potential risk of bias that women who completed the postnatal MHQ were more likely to do so because their symptoms were much greater or differed in ethnicity or age. Baseline characteristics of the women who completed the postnatal MHQ by attending the hospital clinic appointment were compared to those who completed the MHQ by post. A significantly higher proportion of women attending the hospital clinic appointment had known antenatal anal sphincter abnormalities, otherwise all other maternal, neonatal and OASIS baseline characteristics were the same. Bowel symptoms and QoL between the two groups were all comparable. These findings reduce the potential risk of bias that women who completed the postnatal MHQ by attending the hospital clinic appointment were likely to have greater bowel symptoms and a more negative QoL than those who completed the MHQ by post. Baseline characteristics of the women who underwent a vaginal study birth compared to those who had a caesarean section showed expected differences. A significantly higher proportion of women having a vaginal study birth had previously had a vaginal interval birth. Also a significantly higher proportion of women undergoing a caesarean section for the study birth had bowel symptoms, anal sphincter abnormalities and a negative QoL

scores for two of the domains. Consequently, it is reasonable that the findings from our study can be generalised.

A further strength of this study is that it satisfies all of the STROBE checklist requirements. None of the other similar studies, all published since 2007 when the STROBE checklist was introduced (118), have reported compliance to this checklist (44, 88, 92-94). Consequently this study is of high methodological quality that limits bias and satisfies the research recommendations resultant from the systematic review undertaken in chapter three by providing a well conducted, appropriately sized cohort study of women with previous OASIS undergoing subsequent birth, with primary objectives of assessment of anal function, QoL and sphincter anatomy both before and after the intervention.

For women in this study, all EAUS and pre-birth counselling regarding mode of study birth was undertaken by one single clinician, (Specialist Perineal Midwife and author of this thesis who has undertaken all of the studies encompassed within). This strengthens the study findings as it demonstrates consistency within the assessments and the advice given by reducing inter-rater variability, a limitation that was recognised by Fitzpatrick et al (2016) for their study whereby EAUS were undertaken by a number of clinicians (94). Interestingly, in this study out of the eight women that had changes diagnosed in sphincter muscle integrity following the study birth, the changes (either a newly found excessive scarring or defects or no sphincter abnormality that had been seen previously) cannot be accounted for in five of the women as either new occult injuries from the vaginal study birth or from a repeat OASIS repair. These changes are therefore the result of scan image interpretation.

Overall, consistency of scan images prior to and following the study birth in this study was 95.3%, which is in keeping with the generally accepted rate of EAUS image interpretation accuracy of 95% (119).

This study also reports on the impact of the subsequent birth for all of the women in the cohort. Labour and birth is a dynamic process and consequently not all women will achieve the birth mode they were pursuing, demonstrated by ten women in our study. It is therefore vital that when investigating the impact of a subsequent birth of women with previous OASIS these groups of women are included. Similar studies have also done this (88, 94, 99). However, Scheer et al (2009) only included women in their study who had the recommended mode of birth with the rationale that this provides a 'meaningful interpretation'(44) . However, this research methodology will only provide data to support or refute the management protocol used within that study and does not contribute to providing evidence for women prior to the birth on the possible consequences of a birth mode that is not as planned.

As discussed in section 1.1 the RCOG Green-top guidelines for the evidence based identification, repair and management of OASIS was first published in July 2001. These were incorporated into the local clinical guidelines for repair of OASIS at the Trust in which this study was undertaken immediately following publication. Comprehensive audits are regularly undertaken to ensure compliance with local guidelines for clinical negligence legislation purposes. There is a strong need for future ongoing research studies that recognise this improvement in repair technique as it may have implications for ongoing bowel function and QoL. There is currently no other published study that has acknowledged this important gap in the literature.

A strength of this study is that 97.6% of the women in this study sustained and had OASIS repaired following the introduction of the RCOG Green-top guideline in 2001 and multivariate analyses of a sub-cohort of these women demonstrated very similar results to those of the full cohort. Therefore, the findings from this study on the impact of a subsequent birth and its mode on change in bowel function and QoL and the association between anal sphincter muscle integrity following the subsequent birth and its mode on changes in bowel function and QoL can be used for the counselling of the current generation of women in women who had previously sustained an OASIS when deciding on subsequent birth mode.

There is also, currently, very limited published literature discussing the reasons underlying women's' decisions to pursue a chosen mode of subsequent birth. For women in this study a third requested an elective caesarean section and two thirds chose to pursue a vaginal birth. There are currently very limited published findings that have looked at maternal preference regarding mode of subsequent birth. In a cohort study of 557 women undertaken to assess the continence of women with a previous OASIS prior to and following a subsequent birth, Fitzpatrick et al (2016) found that of the 104 women whose mode of birth was equivocal (the presence of symptoms but no anal sphincter defects on EAUS), 56% decided to deliver vaginally and 44% elected for a caesarean section (94). Faltin et al (2005) surveyed 120 women with previous OASIS during their subsequent pregnancy about their preferred mode of birth and found that 65% of the women wanted another vaginal birth, 23% were uncertain, and 11% preferred a caesarean section (64). This study and that of Faltin et al (2005) cannot be directly compared as the women's choice in

this study was recorded following consultation whereas the women in Faltin's study voiced their chosen method prior to any investigation. However, it is interesting that for all of the three studies the number of women requesting a vaginal birth is still similar at over 60% and reinforces the fact that sustaining an OASIS is not a deterrent for pursuing another vaginal birth.

A possible limitation of this study is the six month time point chosen for follow up review following the subsequent birth. It could be argued that hormonal changes influence bowel function during the postnatal period and it would not be unreasonable to expect bowel function at six months post-partum to be not as stable as bowel function at over 12 months post-partum. However, as the study in chapter three and previous research has shown, 70-80% of women who sustain OASIS do not have bowel symptoms at three month post-partum (81, 86, 105, 106). Therefore, a six month review period should allow capture of bowel function and QoL more representative of a non-pregnant state. Also, as discussed during section 4.10 ethical approval was gained for women to consent to be contacted over the longer term and ongoing review for women in this study is planned at both 5 years and 10 year time points. Consequently, data provided from these follow-up studies will reduce this current study limitation.

Also, due to the number of events of bowel symptoms, a limitation to this study is that the results of some of the multivariate analyses must be reviewed with caution as the confidence intervals are large and therefore precision of the estimates is low. However, despite this reservation, in view of the absence of other published study

findings of methodological rigor, the findings from this study remain valid and add considerably to the available evidence.

4.12.2 Summary

This large study adds to the limited data that is currently available investigating the impact of a subsequent birth and its mode on change in bowel function and QoL in women who had previously sustained an OASIS.

At the time of the postnatal MHQ completion following the study birth 76.8% of the women had bowel urgency, 56.0% poor control of flatus, 34.4% difficulty in wiping clean and 23.2% an episode of faecal leakage. Passive leakage was rare (3%) with faecal leakage occurring most often with coughing/sneezing (13.6%).

Whether bowel symptoms might worsen is important to women who have had OASIS when planning subsequent birth.

This study has shown that around half or greater had no change in bowel symptoms; faecal urgency (46.4%) poor control of flatus (56.0%), difficulty in wiping clean (92.8%) and faecal leakage (68.0%). Interestingly, for almost all bowel symptoms a greater proportion of women had an improvement in their bowel symptom occurrence than worsening. The only exception was for faecal leakage during sexual intercourse which was only experienced by a very small number of women

Similarly, for quality of life, across the nine domains the majority of the women (57.6-86.4%), had no change in their QoL after their birth. Again, in all but one of the nine

MHQ QoL domains a higher proportion of women had an improved score following the study birth than a worsened score.

This study also investigated whether the actual mode of study birth was associated with changes in bowel function and QoL and showed that there was no association between whether the birth was vaginal or caesarean section and a worsening, no change or improvement of bowel symptoms for any of the nine MHQ QoL domains.

It is also important to know the role of extensive scarring or anal sphincter defects. The study has shown that mode of study birth had no significant association between worsening, no change or improvement in bowel symptoms or QoL, whether an anal sphincter defect or extensive scarring were present or not. However, for the women who had no anal sphincter defect, mode of birth was of significance for the QoL domain of ‘Physical Limitations’.

These findings have important implications for clinicians caring for women with a previous OASIS considering a subsequent pregnancy.

5 THESIS DISCUSSION AND CONCLUSION

5.1 Discussion of overall thesis findings

The work in this thesis was undertaken to investigate the impact of subsequent birth on bowel function and QoL for women with a previous OASIS in order to provide better evidence than is currently available and that is recognised as needed, to assist clinicians and women with previous OASIS when considering and planning mode of birth during a subsequent pregnancy. This question arose from clear concerns of the women attending the author's specialist clinics.

The systematic review and meta-analysis of the published literature undertaken in chapter two demonstrated two important findings; firstly, that, due to the poor methodological quality and overall heterogeneity of the current available published studies, it was not possible to determine long-term impact or the optimal mode of subsequent births for all women with previous OASIS and better data were needed. Secondly, until better evidence is available, the current available literature did support the current RCOG recommendation of a subsequent vaginal birth for women with previous OASIS who demonstrate no bowel symptoms or sphincter defects as an acceptable option.

To understand the impact of subsequent birth for women with a previous OASIS on long-term outcomes the natural history of this type of trauma needs to be investigated. Therefore a follow-up postal study was undertaken (chapter three) that showed an increase in the incidence in bowel symptoms in women with previous OASIS over the longer term and that bowel symptoms experienced in the short-term

were significantly associated with long-term bowel symptoms and QoL. This finding demonstrates the importance of a thorough review in the postnatal period for all women following sustaining an OASIS to accurately record the presence of any bowel symptoms.

The prospective cohort study undertaken to assess the impact of a subsequent birth and its mode on change in bowel function and QoL in pregnant women who had previously sustained OASIS(chapter four), has provided much needed evidence. It has shown that although bowel symptoms present at antenatal MHQ completion may not contribute largely to a negative impact on the current antenatal QoL, they are all significant characteristics for ongoing bowel symptoms following the subsequent birth, the presence of which is associated with long-term negative QoL domains and hence can serve as a predictor of women at risk of poorer outcomes in the longer-term. This thesis also reinforces the importance of measures of QoL as an indicator of long-term outcome, rather than symptoms in isolation, as four-fifths of women who reported no negative impact on any of the nine QoL domains were experiencing at least one bowel symptom.

Within the two empirical studies undertaken in this thesis, women with previous OASIS in their subsequent pregnancy were advised on the most suitable mode of subsequent birth using the only available current guidance from the RCOG Green-top guideline (40), namely 'all women who have sustained OASIS in a previous pregnancy and who are symptomatic or have abnormal EAUS and/or manometry should be counselled regarding the option of elective caesarean section'. This guidance statement thereby inferring that a vaginal birth is suitable for the remaining

women (i.e. women with previous OASIS with no bowel symptoms and normal EAUS and/or manometry findings), that was the hypothesis underpinning the work in this thesis (as discussed in section 1.5). However, women with previous OASIS can be placed into one of the following four groups:

1. Women with normal bowel function and normal EAUS findings
2. Women with normal bowel function and abnormal EAUS findings
3. Women with abnormal bowel function and normal EAUS findings
4. Women with abnormal bowel function and abnormal EAUS findings

The prospective cohort study undertaken in chapter four of this thesis that satisfies all of the methodological and quality standards found lacking in previously available studies, provides good evidence that for women with a previous OASIS who have normal bowel function and normal EAUS (Group 1), the decision to pursue a subsequent vaginal birth was not associated with worsening of bowel symptoms or a negative QoL. As previously discussed in chapter two (section 2.3.1), a meta-analysis of six cohort NRSs (76, 80, 84, 85, 87, 89), that satisfied inclusion criteria for the systematic review did not demonstrate any significant change in reported worsening of bowel symptoms in women with previous OASIS following a subsequent vaginal birth (131 women; OR 1.36; 95% CI 0.723-2.59; I^2=0%; Figure 2.6). This meta-analysis was re-run with inclusion of the data from the cohort study in this thesis for the 74 women who had a vaginal study birth. This showed that there was still no significant reported worsening of bowel symptoms for women with a previous OASIS following the subsequent vaginal birth (seven studies, 235 women; OR 1.23; 95% CI 0.65-2.30; I^2=21%; Figure 5.1).

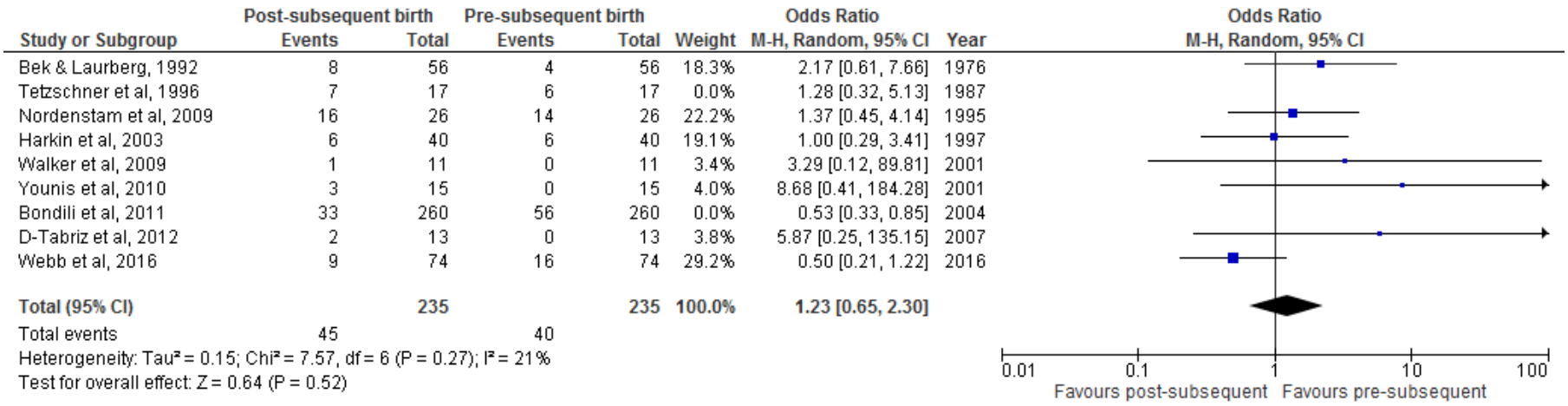


Figure 5.1 Incidence of worsening or de novo symptoms of AI in women with previous OASIS: pre- versus post-subsequent vaginal birth

Also, as previously discussed in section 2.3.3, meta-analysis of three cohort NRSs (86, 92, 93), that were suitable for inclusion in the systematic review did not demonstrate any difference in de novo AI or worsening of symptoms in women with previous OASIS following subsequent vaginal birth relative to a subsequent caesarean section (three studies, 199 women; OR 0.63; 95% CI 0.21-1.88; I^2 = 0%; Figure 2.7). This meta-analysis was re-run with the inclusion of the data from the cohort study within this thesis (Chapter four), and strengthened the case of support for no demonstrable preferable mode of subsequent birth in regard to de novo or worsening bowel symptoms for women with a previous OASIS (four studies, 320 women; OR 0.96; 95% CI 0.42-2.20; I^2=0%; Figure 5.2).

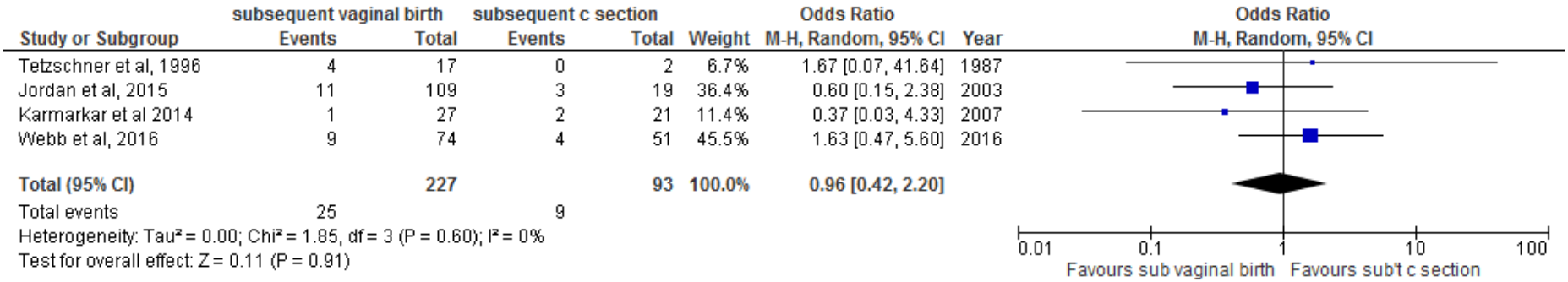


Figure 5.2 Incidence of worsening or de novo symptoms of AI in women with previous OASIS: subsequent vaginal birth versus subsequent caesarean section

This information is very important to enable women to make an informed choice and support them in their decision to aim for a subsequent vaginal birth. However, the study has not been powered to provide the appropriate level of evidence to support the most suitable mode of birth for women with a previous OASIS who fall into the remaining groups (Groups 2-4). Consequently, further research is needed to investigate the most suitable mode of subsequent birth for women with previous OASIS who have abnormal bowel function and/or abnormal EAUS. It is likely such a study will present challenges for recruitment as women with bowel symptoms and/or abnormal EAUS may, understandably, be reluctant to pursue a vaginal birth when the implications of worsening of bowel symptoms and/or further damage to the anal sphincter may occur. Therefore, regardless of how the research is undertaken (either as an RCT or as a cohort study), to ensure timely conclusion and reach the necessary power to address important outcomes it is likely that such research will need to be multi-centre/international. Until studies are undertaken to investigate the most suitable mode of subsequent birth for these other women, clinicians can only offer guidance that a caesarean section remains a suitable mode of birth for women with a previous OASIS who do not have normal bowel function *and* normal EAUS findings, but this is based on limited evidence.

5.1.1 Strengths and limitations

The extensive work in this thesis has several strengths. The studies included in this thesis have highlighted a very important aspect; that the mode of subsequent birth is an important characteristic, but the mode of subsequent birth 'per se' is not the determining characteristic for ongoing bowel function and quality of life. Findings

from this study have clearly demonstrated that for women with previous OASIS, the presence of bowel symptoms prior to the subsequent birth are significantly associated with bowel symptoms and negative impact on many QoL domains following any subsequent birth. This supports the view that women who sustain an OASIS should be seen in specialised clinics both for their initial postnatal follow-up and in any subsequent pregnancy to ensure that their bowel symptoms are properly explored, managed and taken into consideration when counselled about the most suitable mode of subsequent birth.

Another strength is that within the two cohort studies undertaken in this thesis, over 97% of the women had sustained and had their OASIS repaired following the introduction of the RCOG Green-top guideline in 2001 and multivariate analyses of a sub-cohort of these women demonstrated very similar results to those of the full cohort for both cohort studies. Therefore, the findings from the work in this thesis on the impact of a subsequent birth and its mode on change in bowel function and QoL and the association between anal sphincter muscle integrity following the subsequent birth and its mode on changes in bowel function and QoL can be used for the counselling of the current generation of women in women who had previously sustained an OASIS when deciding on subsequent birth mode. This provides much needed evidence that the systematic review undertaken in chapter two identified as currently lacking as, of the published studies currently available, data for the majority of women included in the studies are for women who sustained their OASIS prior to the introduction of the RCOG Green-top evidence based repair recommendations in 2001. It has also highlighted that, in order to allow a better understanding of the

longer term impact of OASIS on bowel function and QoL and reduce bias from now outdated repair methods there is a need for more studies undertaking ongoing longer-term follow up of women for whom OASIS management has been in line with the RCOG Green-top guidelines. If undertaken at regular period follow up time points, these data would provide valuable information regarding the long-term outcome of OASIS throughout the woman's lifetime.

The two empirical studies undertaken within this thesis were constructed with an overriding biomedical approach as they were investigating changes in bowel anatomy and physiology and such an approach helps to elucidate the relationship between disease and outcome. However, a limitation of the biomedical approach to this research was that the women's views were not investigated. Although the cohort study undertaken in chapter four did ask the women's reasons behind their choice of subsequent birth mode but this was based on a discussion during the clinical counselling appointment and did not use a qualitative methodologically structured interview. Also, although both cohort studies investigated the impact on QoL for women with previous OASIS that the systematic review undertaken in chapter two identified as an area where evidence was lacking, these studies did not pursue a deeper understanding of the reasons underpinning changes in perceptions of bowel symptoms and/or QoL that can manifest as worsening or improvements. As discussed in section 4.12, there is currently very limited published literature discussing the reasons underlying women's' decisions to pursue a chosen mode of subsequent birth. Consequently, it is important that any future research into mode of

subsequent birth for women with previous OASIS is designed to include a qualitative element to provide this much needed evidence.

As discussed in section 1.3, the Manchester Health Questionnaire (MHQ) was chosen for use in both empirical studies undertaken in this thesis. Although it was the most appropriate valid, reliable and responsive questionnaire available to assess AI and QoL in women it did have limitations. It is a lengthy questionnaire and it captures bowel symptoms (faecal urgency, difficulty wiping, poor control of flatus, faecal incontinence) through an index that asks women to select frequency of bowel symptoms as 'Never', 'Occasionally', 'Sometimes', 'Most of the time', and 'All of the time'. This grading system, although it has been validated, does not give much gradient between the frequencies of 'Occasionally' and 'Sometimes'. It also requests bowel function over the four week period prior to the day of questionnaire completion. Due to the cohort sample size and small number of women experiencing some of the bowel symptom frequencies, to allow multivariate analysis it was necessary to dichotomise symptoms into either 'present' or 'absent'. Typical anal physiology means that, over a four week period the majority of women who regard their bowel function as 'normal' will have the presence of one of the bowel symptoms (such as faecal urgency, poor control of flatus), albeit at a very low frequency (such as 'Occasionally'). Consequently, some women will be classified as having a bowel symptom but regard their bowel function as normal. The lack of questionnaires currently available for women with AI as identified in section 1.3 and the limitations encountered with using the MHQ within the studies within this thesis certainly support the need for development of a new questionnaire to capture bowel

symptoms and QoL for women that can be used in future research or as a means of identifying women with problems to allow appropriate treatment.

5.2 Overall thesis conclusion

Obstetric anal sphincter injuries (OASIS) are serious complications of vaginal birth with a reported average worldwide incidence of 4%-6%. They are recognised to be a major risk characteristic of AI resulting in concern amongst some women who have previously sustained an OASIS when considering the most suitable mode of birth in a subsequent pregnancy and its impact on symptoms at long-term.

A systematic review and meta-analysis of the published literature regarding the impact of a subsequent birth and it's mode on bowel symptoms and/or QoL for women with previous OASIS, was performed. This demonstrated that, due to the poor methodological quality and overall heterogeneity of the current available published studies, it is not possible to determine long-term impact or the optimal mode of subsequent births for all women with previous OASIS and better data are needed. However, it did support the current RCOG recommendation of a subsequent vaginal birth for women with previous OASIS who demonstrate no bowel symptoms or sphincter defects.

The impact of subsequent birth on long-term outcomes cannot be viewed in isolation without understanding the natural history of this type of trauma. Therefore a follow-up postal study was undertaken that demonstrated an increase in incidence in bowel symptoms in women with previous OASIS over the longer term and that bowel

symptoms experienced at the short-term are significantly associated with long-term bowel symptoms and QoL.

Finally, a prospective cohort study of 175 women with previous OASIS was also undertaken to assess the impact of a subsequent birth and its mode on change in bowel function and QoL in newly pregnant women who had previously sustained OASIS. This study showed that the mode of subsequent birth (vaginal or caesarean) was not a significant independent predictor of bowel symptoms or having a negative impact on QoL for women with previous OASIS.

The work included in this thesis demonstrates the importance of specialist review and identification of bowel symptoms for women who sustain an OASIS both immediately following the birth and longer-term when deciding on subsequent birth mode. Findings from the cohort study that satisfied all of the methodological and quality standards found lacking in currently available studies show that for women with previous OASIS who have normal bowel function and normal anal sphincter anatomy a subsequent vaginal birth is suitable.

Appendix 1.1 RCOG Green-top Guidelines standardised evidence levels and grades of recommendations

Classification of evidence levels

1++	High-quality meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias
1–	Meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a high risk of bias
2++	High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2–	Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytical studies, e.g. case reports, case series
4	Expert opinion

Grades of recommendations

A	At least one meta-analysis, systematic review or randomised controlled trial rated as 1++, and directly applicable to the target population; or A systematic review of randomised controlled trials or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+ directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+

Good practice point

✓	Recommended best practice based on the clinical experience of the guideline development group

Appendix 1.2 Manchester Health Questionnaire (MHQ) – Scoring calculation

QoL domain scores:

1. General Health Perceptions
   Score = ((score to Question 1-1)/4) x 100

2. Incontinence Impact
   Score = ((score to Question 2-1)/4) x 100

3. Role Limitations
   Score = (((score to Question 13+14)-2/8) x 100

4. Physical Limitations
   Score = (((score to Question 15+16)-2)/8) x 100

5. Social Limitations
   Score = (((score to Question 17+18+21*)-3)/12) x 100

   * If Question 21 is not answered then subtract 2 and divide by 8

6. Personal Relationships
   Score = (((score to Question 19+20#)-2)/12) x 100

   # If only Question 19 or 20 is answered then subtract 1 and divide by 4

   Questions 19 and 20 might not be answered at all , then not applicable

7. Emotions
   Score = (((score to Question 22+23+24)-3)/12) x 100

8. Sleep/Energy
   Score = (((score to Question 25+26)-2)/8) x 100

9. Severity Measures
   Score = (((score to Question 27+28+29+30+31)-5)/20) x 100

Bowel Symptoms Index

Questions 3-12 are not routinely scored but act as a guide to symptomatology.

Appendix 2.1 PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5-6
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6-7

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7-8
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	7-8

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7-8
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	7-8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8-9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	9-14
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	9-14
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	9-14
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	9-14

Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	9-14
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14-17
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14-17
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	17-18
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	19

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

Appendix 2.2 Medline search strategies

Bowel function:

1. ANAL CANAL/in [in=Injuries].
2. exp OBSTETRIC LABOR COMPLICATIONS/.
3. 1 AND 2
4. (obstetric* AND anal AND sphincter AND injur*).ti,ab
5. OASIS.ti,ab
6. ((third OR 3rd OR fourth OR 4th) AND degree AND (perineal OR perineum) AND (tear* OR injur* OR trauma)).ti,ab
7. PERINEUM/in [in=Injuries]
8. exp PERINEUM/
9. exp WOUNDS AND INJURIES/
10. 8 AND 9
11. 7 OR 10
12. ((third OR 3rd OR fourth OR 4th) AND degree).ti,ab
13. 11 AND 12
14. 6 OR 13
15. 3 OR 4 OR 5 OR 14
16. exp DEFECATION/
17. exp FECAL INCONTINENCE/
18. ((fecal OR faecal OR anal) AND (incontinen*)).ti,ab
19. ((bowel OR anal) AND (funtion* OR symptom*)).ti,ab
20. 16 OR 17 OR 18 OR 19
21. 15 AND 20.
22. Duplicate filtered: [15 AND 20]

Quality of life
1. ANAL CANAL/in [in=Injuries
2. exp OBSTETRIC LABOR COMPLICATIONS/
3. 1 AND 2
4. (obstetric* AND anal AND sphincter AND injur*).ti,ab; 254 results.
5. OASIS.ti,ab
6. ((third OR 3rd OR fourth OR 4th) AND degree AND (perineal OR perineum) AND (tear* OR injur* OR trauma)).ti,ab
7. PERINEUM/in [in=Injuries]
8. exp PERINEUM/
9. exp WOUNDS AND INJURIES/
10. 8 AND 9
11. 7 OR 10
12. ((third OR 3rd OR fourth OR 4th) AND degree).ti,ab
13. 11 AND 12
14. 6 OR 13
15. 3 OR 4 OR 5 OR 14
16. exp QUALITY OF LIFE/
17. (qualit* AND life).ti,ab

18. exp QUESTIONNAIRES/
19. (validated AND questionnaire*).ti,ab.
20. 16 OR 17 OR 18 OR 19
21. 15 AND 20
22. Duplicate filtered: [15 AND 20]

Appendix 2.3 Characteristics of all studies included in the systematic review

Authors, country, language, year, reference	Study design & population, data collection and enrolment	Study intention with regards to OASIS	Total number of women at follow up survey with OASIS	Number of women included at follow up survey data with previous OASIS and a subsequent birth, mode of subsequent birth surveyed	Measurement tool, setting	Was a validated measurement tool used, name (if given)?	Subject area	Study 'data period', timing of when survey(s) undertaken	Extracted findings for the impact of subsequent birth on AI/QoL for women with previous OASIS
An, Australia, English, 2014, (90)	Cohort of women sustaining OASIS at one hospital during a set time period identified from hospital database, retrospective, unreported	Impact of subsequent birth on previous OASIS	67	67, vaginal and caesarean section	Verbal Q&A interview, telephone only	Yes, SMIS	Bowel function	2010-2013, initial survey unreported time point following initial OASIS with follow up at unreported time point following subsequent birth	30 women (44.8%) delivered by caesarean section and 37 women (55.2%) delivered vaginally. Recurrent OASIS was 2.7% (1/37). Postpartum SMIS scores were the same/improved in 55/67 (82%) of patients. Predictors of normal continence following subsequent birth were low SMIS score at initial visit [median 0 vs 2(p=0.0002)] and low Norderval score [median 0 vs 1(p=0.037)].
Andrews, England, English, 2013, (105)	Cohort of women having a first vaginal birth during a set time period, prospective, consecutive	Incidence of AI & UI 4yrs post childbirth following accurate diagnosis of perineal trauma	25	15, vaginal and caesarean section	Self-completion questionnaire, mixed outpatient clinic & postal	Yes, MHQ & ICIQ-SF	Bowel function, QoL, sexual function	Jan 2003-2004, initial survey at 1-3 months postnatal following OASIS with follow up at a set 4 year time point	At the 4 year follow up time point no woman had AI and there was no difference in rates of flatus incontinence prior to delivery up to 4 years postpartum regardless of whether OASIS occurred or not

Bek, Denmark, English, 1992, (80)	Cohort of women sustaining OASIS at one hospital during a set time period identified from hospital database, retrospective, consecutive	Impact of subsequent birth on previous OASIS	121	56, vaginal only	Self-completion questionnaire, postal only	Unreported	Bowel function	01.01.76 - 30.10.87, no initial survey with a set time point survey in 1989	23 women (41%) had transient AI directly following OASIS and 4 women (7%) had permanent AI. In the 23 women with transient AI , 9 women (39%; 95% CI 19%-59%) developed AI after the subsequent birth and this was permanent in 4 women (17.4%; 95% CI 2%-33%). Transient AI was significantly associated with development of AI following a subsequent birth (bivariate analysis: OR 8.7; 95% CI 1.9-39; *p*=0.005). Logistic regression and adjustment for other factors showed transient AI was the only factory that increased the risk of AI following subsequent birth (OR 23; 95% CI 3.7-150). In the 29 women without AI after OASIS, 2 women had transient flatus incontinence but for < 14 days following the subsequent birth.
Bondili, England, English, 2011, (88)	Cohort of women attending a specialist OASIS clinic, retrospective, consecutive	Impact of subsequent birth on previous OASIS	260	260, vaginal and caesarean section	Self-completed questionnaire , mixed outpatient clinic & verbal telephone interview for those who did not attend follow up appointment	Unreported	Bowel function	Jan 2004-Dec 2009, initial survey before 28 gestational weeks with follow up at 6-8 weeks postnatal	56/260 women (21.5%) were symptomatic following OASIS and underwent elective caesarean section for subsequent birth. At postnatal review there was an *improvement* in all AI symptom categories: Faecal urgency (39%; 18 vs 11; *p*=0.18) Faecal Incontinence (40%; 15 vs 9; *p*=0.21) Mixed symptoms (42%; 23 vs 13; *p*=0.84)

									Symptomatic (43%; 56 vs 33; *p*=0.0012).
Daly, England, English, 2013, (96)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, consecutive	Impact of subsequent birth on previous OASIS	199	199, vaginal and caesarean section	Self-completion questionnaire, outpatient clinic only	Yes, SMIS	Bowel function	Mar 2003-Dec 2012, initial survey at a mean of 38.4 moths postnatal following OASIS with follow up at 0-6 months postnatal after subsequent birth	156 women had subsequent vaginal birth (152 recommended); 43 women had subsequent caesarean section (23 recommended). There were no significant changes in SMIS scores post vs pre subsequent birth (*p* values not given).
Dilmaghani-Tabriz, England, English, 2012, (85)	Cohort of women with OASIS and subsequent vaginal birth identified from hospital database, retrospective, consecutive	Impact of subsequent birth on previous OASIS	13	13, vaginal only	Self-completion questionnaire, postal only	Unreported	Bowel function	2007-2009, unreported	Flatus incontinence reported in two women (15.3%) after an average of 15 months post subsequent vaginal birth.
De Leeuw JW, Netherlands, English, 2001, (77)	Cohort with matched controls of women with OASIS in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	125	not specified, vaginal and caesarean section	Self-completion questionnaire, postal only	Unreported	Bowel function	01.01.71-31.12.90, no initial survey with set time point survey at 14 years	Subsequent vaginal birth was not associated with the development of AI (41% vs 39% respectively) (OR 2.32; 95% CI 0.85-6.33; *p*=0.10).
Fitzpatrick, Eire, English, 2016, (94)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy,	Impact of subsequent birth on previous OASIS	197	197, vaginal and caesarean section	Self-completion questionnaire, outpatient clinic only	No, 'modified' Jorge & Wexner score	Bowel function	2006-2012, initial survey 28-34 gestational weeks with follow up at 6 months postnatal	No significant change in AI scores of women with previous OASIS who underwent subsequent vaginal delivery (Pre 0.9 vs Post 1.3; *p* value not given).

	prospective, consecutive								Symptoms scores in subgroup of women with subsequent repeat recognised and occult OASIS not significantly higher than those without recurrent OASIS (1.2 vs 1.4; *p* value not given)
Harkin, Eire, English, 2003, (84)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, consecutive	Risk of OASIS recurrence & whether predictable	342	40, vaginal only	Self-completion questionnaire, outpatient clinic only	No	Bowel function	1997-1999, initial survey at 1-3 months postnatal following OASIS with follow up reported as 'postpartum'	No change in the number of symptomatic women following subsequent vaginal birth (n= 6) but worsening of symptoms in 3 women (1 women excluded as related to IBS (responded to treatment / normal RM & EAUS).
Huebner, Germany, English, 2013, (78)	Cohort of women with OASIS in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	99	not specified, vaginal and caesarean section	Verbal Q&A interview, telephone only	No	Bowel function	01.01.74-31.12.83, no initial survey with set time point survey at mean of 27.5 years (+/- 2.4 years)	No association between parity and incontinence of either liquid/solid stool (OR 1.69; 95% CI 0.58-4.97; p=0.335) or flatus (OR 2.25; 95% CI 0.94-5.41; p=0.067).
Jordan, UK, English, 2015, (92)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, consecutive	Impact of subsequent birth on previous OASIS	137	137, vaginal and caesarean section	Self-completion questionnaire, outpatient clinic only	Yes, SMIS	Bowel function	Jan 2003 - Dec 2014, initial survey 28-32 gestational weeks of subsequent pregnancy with follow up survey at 12 weeks post subsequent birth	No significant change in SMIS scores for AI symptoms, for women with previous OASIS undergoing subsequent recommended vaginal birth (p=0.86) or caesarean section (p=0.46). However, worsening of SMIS QoL scores for women undergoing subsequent caesarean section (p=0.02), and significant worsening of AI symptoms in women having a vaginal birth and not recommended caesarean section (p<0.01)

Karmarkar, UK, English, 2015, (120)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, consecutive	Impact of subsequent birth on previous OASIS	50	48, vaginal and caesarean section	Self-completion questionnaire, outpatient clinic only	Yes, unreported	Bowel function	Jan 2006 - Mar 2013, initial survey 8-12 weeks following OASIS, then seen in second trimester of subsequent pregnancy and at 8-12 weeks post subsequent birth	No worsening of AI symptoms in a/symptomatic women undergoing subsequent planned vaginal birth (n=26) and elective caesarean section (n=19), however, worsening of AI symptoms in symptomatic women achieving a non-planned vaginal birth (n=1) and emergency caesarean section (n=2)
Kumar, England, English, 2012, (73)	Cohort of women with OASIS in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	41	25, vaginal and caesarean section	Self-completion questionnaire, postal only	No	Bowel function, QoL	2004, no initial survey with set time point survey at mean of 5 years	Of the 25 women with previous OASIS who underwent a further pregnancy, 19 (76%) were asymptomatic (p=0.03).
Naidu, England, English, 2015, (91)	Case-control of women with two subsequent OASIS, attending specialist OASIS clinic in subsequent pregnancy , prospective, consecutive	Outcome of anal function following two OASIS	33	33, vaginal only	Self-completion questionnaire, outpatient clinic only	Yes, SMIS	Bowel function, QoL	Jan 2003 - Dec 2014, initial survey 28-32 gestational weeks of subsequent pregnancy with follow up survey at 8-12 weeks post subsequent birth	No significant clinical deterioration of anal symptoms, anorectal function or SMIS scores depicting impact on QoL, for women following a second OASIS and between case and control groups.
Nordenstam, Sweden, English, 2009, (76)	Cohort of women nulliparous women having a vaginal birth in a set time period, prospective, unreported	Natural progression of AI after childbirth	27	26, vaginal only	Self-completion questionnaire, postal only	Yes, Osterberg et al 1996	Bowel function	1995, initial survey 3 days postnatal with follow up surveys at 9 months, 5 years and 10 years	AI significantly more frequent in women with OASIS and subsequent birth vs women with no previous OASIS and a subsequent birth @ <u>9 months:</u> 14/26 (54%) vs 38/164 (23%) (no p values given) <u>5 years;</u> 16/25 (64%) vs 43/146 (29%) (no p values given) <u>10 years</u>: 16/26 (62%) vs 51/169 (30%)

									(*p* =0.01) AI significantly more frequent in women with OASIS and subsequent birth vs women with OASIS and no subsequent birth @ <u>5 years;</u> 16/25 (64%) vs 0/4 (0%) (no *p* values given) Severe AI significantly more frequent in women with OASIS and subsequent birth vs women with no previous OASIS and a subsequent birth @ <u>5 years;</u> 11/25 (44%) vs 18/146 (12%) (no *p* values given)
Poen, Netherlands, English, 1998, (82)	Cohort of women with OASIS in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	117	43, vaginal and caesarean section	Self-completion questionnaire, mixed outpatient clinic and postal	Unreported	Bowel function, QoL, sexual function	1985-1994, no initial survey with set time point survey at mean of 4.8 years (0.8-11.3)	Higher incidence of reported symptoms of AI in women with subsequent birth (24/43; 56%) versus those without (23/67; 34%) RR 1.6; 95%CI 1.1-2.5; *p*=0.025
Reid, England, English, 2014, (81)	Cohort of women attending a specialist OASIS clinic, prospective, consecutive	Period follow up on primary OASIS	344	92, vaginal and caesarean section	Self-completed questionnaire, mixed outpatient clinic & verbal telephone interview for those who did not attend follow up appointment	SMIS, MHQ	Bowel function, QoL	01.07.02-31.12.07, initial survey at 9 weeks postnatal following OASIS and then set time point survey in June 2008 with mean of 3.2 ± 1.6 years	Higher incidence of reported symptoms of AI at three years following initial OASIS in women with subsequent caesarean section* (5/24; 20.8%) versus those with subsequent vaginal birth (2/68; 2.9%) *p*=0.012 * 1 woman persistent AI (at 9 weeks and 3 years), 4 women with de novo symptoms of AI

Sangalli, Switzerland, English, 2000, (75)	Cohort of women with OASIS in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	177	114, vaginal only	Self-completion questionnaire, postal only	No	Bowel function	01.01.82-31.12.83, no initial survey with set time point survey July -Dec 1995	Decrease in prevalence and no worsening of AI symptoms in women with previous 3rd degree OASIS undergoing a subsequent vaginal birth. However, for women with previous 4th degree OASIS, subsequent vaginal birth has an increased risk of severe incontinence (*p*=0.043).
Scheer, England, English, 2009, (44)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, consecutive	Impact of subsequent birth on previous OASIS	59	56, vaginal and caesarean section	Self-completion questionnaire, outpatient clinic only	Yes, MHQ & Wexner & Rockwood et al 2000	Bowel function, QoL, sexual function	Aug 2002-Oct 2006, initial survey prior to 36 gestational weeks of subsequent pregnancy with follow up at 0-6 months postnatal after subsequent birth	Improvement in all symptoms of AI except solid incontinence (no change), after subsequent vaginal birth (n=35). Anorectal manometry pressures did not change significantly following recommended vaginal birth (n=35) or recommended caesarean section (n=9). Sub-analysis of women with sphincter defects: Significantly reduced squeeze pressure following subsequent caesarean section (n=9; *p*=0.006). Significant reduction in squeeze pressure increment following subsequent vaginal birth (n=13; *p*=0.034). Significant improvement in QoL domains of incontinence impact (p=0.029) and emotions (p=0.008) for all women following subsequent birth when compared to scores in the antenatal period. (no significant change in other domains).

									A significant negative impact on three QoL domains post birth; incontinence impact (p=0.012), emotions (p=0.003) and severity measures (p=0.032), for women having recommended subsequent caesarean section (n=9) versus women having recommended vaginal birth (n=35).
Soerensesn, Denmark, English, 2013, (79)	Cohort of women with OASIS(3c & 4th degree only) in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	125	93, vaginal and caesarean section	Self-completion questionnaire, postal only	Yes	Bowel function, QoL, sexual function	01.01.96-30.10.87, no initial survey with set time point survey at mean of 22.1 years (21.4-23.0)	No significant association between long-term AI and having a subsequent birth in women with 3c or 4th degree OASIS.
Sze, USA, English, 2005, (74)	Cohort of women with OASIS (4th degree only)in a set time period identified by database, retrospective, consecutive	Impact of subsequent birth on previous OASIS	148	96, vaginal only	Verbal Q&A interview, telephone only	No, 'questions were composed with terminology of Pescorati'	Bowel function, QoL	Jan 1984-Jun 2000, no initial survey but set time point survey varying with parity	Women with previous 4th degree OASIS who had ≥ 2 subsequent vaginal births, severity of AI symptoms (p=0.012) and severity of impact on daily QoL (p<0.001) were both significantly higher compared to women with 0 or 1 subsequent birth.
Sze, USA, English, 2005, (72)	Cohort of women with OASIS (3rd degree only) in a set time period identified by database, retrospective, consecutive	Impact of subsequent birth on previous OASIS & impact of another complete OASIS	211	141, vaginal only	Verbal interview , telephone only	No, 'questions were composed with terminology of Pescorati'	Bowel function, QoL	Jan 1984-Jun 1999, no initial survey but set time point survey varying with parity	Incidence of and severe symptoms of AI were similar in women with previous 3rd degree OASIS who had 0, 1 and ≥ 2 subsequent vaginal births (11/65, 11/67, 12/40, p=0.179; 2/65, 1/67, 2/40, p=0.811). Incidence of and severe symptoms of AI were similar in women with previous 3rd degree OASIS and no subsequent birth versus women with two OASIS and ≥

									2 subsequent vaginal births (11/65, 10/37, *p*=0.225; 2/65, 2/37, *p*=0.46)
Tetzschner, Denmark, English, 1996, (86)	Cohort of women with previous OASIS attending specialist OASIS clinic, prospective, consecutive	Period follow up on primary OASIS	72	19, vaginal and caesarean section	Self-completion questionnaire, mixed outpatient clinic and postal	No	Bowel function	Unreported, initial survey at 1-3 months postnatal following OASIS with set time point survey at 2-4 years	Of women with subsequent vaginal birth (17/19), 4 (24%) had aggravation of AI symptoms (flatus incontinence)
Visscher, Netherlands, English, 2014, (83)	Cohort of women with previous OASIS (excluding 3a & women with no AI at 2 months postnatal) attending specialist clinic in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	40	15, vaginal and caesarean section	Self-completion questionnaire, postal only	Mixed variety of questionnaires used: Parks; Vaizey, Wexner, ICIQ-SF, FSFI	Bowel function, QoL, sexual function, urinary incontinence	1998-2008, initial survey at 3 months postnatal following OASIS with set time point survey September 2011 at 5 years (range 2.4-11.4 years)	Increase in incidence of incontinence in women with subsequent births (n=15) versus women without subsequent births (n=25) (*p*=0.008).
Wagenius, Sweden, English, 2003, (102)	Case-control of women with OASIS in a set time period identified by database , retrospective, consecutive	Period follow up on primary OASIS & Impact of subsequent birth on perineal trauma for previous OASIS	186	61, vaginal only	Self-completion questionnaire, postal only	No, 'modified' Pescorati	Bowel function, QoL, sexual function	1994-1997, no initial survey but set time point survey varying at 4 years	Of women with subsequent vaginal birth (57/61) 5 women (9%) reported impaired AI after the subsequent birth.

Walker, England, English, 2009, (87)	Cohort of women with previous OASIS and having a subsequent vaginal birth in a set time period identified by database, retrospective, consecutive	Impact of subsequent birth on previous OASIS	39	11, vaginal only	Unreported, outpatient clinic only	Unreported	Bowel function	Nov 2001-Nov 2007 , no initial survey but set time point survey at unreported time	Of women with subsequent vaginal birth 64% (7/11) had deterioration of EAUS/ARP findings. Only 1 woman developed AI symptoms (flatus incontinence)
Younis, England, English, 2010, (89)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, unreported	Impact of subsequent birth on previous OASIS	43	15, vaginal only	Unreported, outpatient clinic only	Unreported	Bowel function	Nov 2001-Nov 2007 , no initial survey but set time point survey at unreported time	Of women with subsequent vaginal birth 20% (3/15) developed AI symptoms (2 x flatus incontinence; 1 x faecal urgency)

Appendix 2.4 Characteristics of the studies included in the systematic review meta analyses

Authors, country, language, year, reference	Study design & population, data collection and enrolment	Study intention with regards to OASIS	Total number of women at follow up survey with OASIS	Number of women included at follow up survey data with previous OASIS and a subsequent birth, mode of subsequent birth surveyed	Measurement tool, setting	Was a validated measurement tool used, name (if given)?	Subject area	Study 'data period', timing of when survey(s) undertaken	Extracted findings for the impact of subsequent birth on AI/QoL for women with previous OASIS
Meta-analysis of studies on reported incidence of AI in women with previous OASIS: no subsequent birth versus subsequent birth (Figure 2.3)									
Kumar, England, English, 2012, (73)	Cohort of women with OASIS in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	41	25, vaginal and caesarean section	Self-completion questionnaire, postal only	No	Bowel function, QoL	2004, no initial survey with set time point survey at mean of 5 years	Of the 25 women with previous OASIS who underwent a further pregnancy, 19 (76%) were asymptomatic (p=0.03).

Nordenstam, Sweden, English, 2009, (76)	Cohort of women nulliparous women having a vaginal birth in a set time period, prospective, unreported	Natural progression of AI after childbirth	27	26, vaginal only	Self-completion questionnaire, postal only	Yes, Osterberg et al 1996	Bowel function	1995, initial survey 3 days postnatal with follow up surveys at 9 months, 5 years and 10 years	AI significantly more frequent in women with OASIS and subsequent birth vs women with no previous OASIS and a subsequent birth @ 9 months: 14/26 (54%) vs 38/164 (23%) (no *p* values given) 5 years: 16/25 (64%) vs 43/146 (29%) (no *p* values given) 10 years: 16/26 (62%) vs 51/169 (30%) (*p* =0.01) AI significantly more frequent in women with OASIS and subsequent birth vs women with OASIS and no subsequent birth @ 5 years: 16/25 (64%) vs 0/4 (0%) (no *p* values given) Severe AI significantly more frequent in women with OASIS and subsequent birth vs women with no previous OASIS and a subsequent birth @ 5 years: 11/25 (44%) vs 18/146 (12%) (no *p* values given)

Sze, USA, English, 2005, (74)	Cohort of women with OASIS (4th degree only)in a set time period identified by database, retrospective, consecutive	Impact of subsequent birth on previous OASIS	148	96, vaginal only	Verbal Q&A interview, telephone only	No, 'questions were composed with terminology of Pescorati'	Bowel function, QoL	Jan 1984-Jun 2000, no initial survey but set time point survey varying with parity	Women with previous 4th degree OASIS who had ≥ 2 subsequent vaginal births, severity of AI symptoms (p=0.012) and severity of impact on daily QoL (p<0.001) were both significantly higher compared to women with 0 or 1 subsequent birth.
Sze, USA, English, 2005, (72)	Cohort of women with OASIS (3rd degree only) in a set time period identified by database, retrospective, consecutive	Impact of subsequent birth on previous OASIS & impact of another complete OASIS	211	141, vaginal only	Verbal interview , telephone only	No, 'questions were composed with terminology of Pescorati'	Bowel function, QoL	Jan 1984-Jun 1999, no initial survey but set time point survey varying with parity	Incidence of and severe symptoms of AI were similar in women with previous 3rd degree OASIS who had 0, 1 and ≥ 2 subsequent vaginal births (11/65, 11/67, 12/40, p=0.179; 2/65, 1/67, 2/40, p=0.811). Incidence of and severe symptoms of AI were similar in women with previous 3rd degree OASIS and no subsequent birth versus women with two OASIS and ≥ 2 subsequent vaginal births (11/65, 10/37, p=0.225; 2/65, 2/37, p=0.46)
Sangalli, Switzerland, English, 2000, (75)	Cohort of women with OASIS in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	177	114, vaginal only	Self-completion questionnaire, postal only	No	Bowel function	01.01.82-31.12.83, no initial survey with set time point survey July -Dec 1995	Decrease in prevalence and no worsening of AI symptoms in women with previous 3rd degree OASIS undergoing a subsequent vaginal birth. However, for women with previous 4th degree OASIS, subsequent vaginal birth has an increased risk of severe incontinence (p=0.043).

Meta-analysis of studies on reported incidence of AI in women with previous OASIS; pre- versus post-subsequent birth (Figure 2.6)

Bek, Denmark, English, 1992, (80)	Cohort of women sustaining OASIS at one hospital during a set time period identified from hospital database, retrospective, consecutive	Impact of subsequent birth on previous OASIS	121	56, vaginal only	Self-completion questionnaire, postal only	Unreported	Bowel function	01.01.76 - 30.10.87, no initial survey with a set time point survey in 1989	23 women (41%) had transient AI directly following OASIS and 4 women (7%) had permanent AI. In the 23 women with transient AI , 9 women (39%; 95% CI 19%-59%) developed AI after the subsequent birth and this was permanent in 4 women (17.4%; 95% CI 2%-33%). Transient AI was significantly associated with development of AI following a subsequent birth (bivariate analysis: OR 8.7; 95% CI 1.9-39; *p*=0.005). Logistic regression and adjustment for other factors showed transient AI was the only factory that increased the risk of AI following subsequent birth (OR 23; 95% CI 3.7-150). In the 29 women without AI after OASIS, 2 women had transient flatus incontinence but for < 14 days following the subsequent birth.
Tetzschner, Denmark, English, 1996, (86)	Cohort of women with previous OASIS attending specialist OASIS clinic, prospective, consecutive	Period follow up on primary OASIS	72	19, vaginal and caesarean section	Self-completion questionnaire, mixed outpatient clinic and postal	No	Bowel function	Unreported, initial survey at 1-3 months postnatal following OASIS with set time point survey at 2-4 years	Of women with subsequent vaginal birth (17/19), 4 (24%) had aggravation of AI symptoms (flatus incontinence)

Nordenstam, Sweden, English, 2009, (76)	Cohort of women nulliparous women having a vaginal birth in a set time period, prospective, unreported	Natural progression of AI after childbirth	27	26, vaginal only	Self-completion questionnaire, postal only	Yes, Osterberg et al 1996	Bowel function	1995, initial survey 3 days postnatal with follow up surveys at 9 months, 5 years and 10 years	AI significantly more frequent in women with OASIS and subsequent birth vs women with no previous OASIS and a subsequent birth @ 9 months: 14/26 (54%) vs 38/164 (23%) (no *p* values given) 5 years; 16/25 (64%) vs 43/146 (29%) (no *p* values given) 10 years: 16/26 (62%) vs 51/169 (30%) (*p* =0.01) AI significantly more frequent in women with OASIS and subsequent birth vs women with OASIS and no subsequent birth @ 5 years; 16/25 (64%) vs 0/4 (0%) (no *p* values given) Severe AI significantly more frequent in women with OASIS and subsequent birth vs women with no previous OASIS and a subsequent birth @ 5 years; 11/25 (44%) vs 18/146 (12%) (no *p* values given)

Harkin, Eire, English, 2003, (84)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, consecutive	Risk of OASIS recurrence & whether predictable	342	40, vaginal only	Self-completion questionnaire, outpatient clinic only	No	Bowel function	1997-1999, initial survey at 1-3 months postnatal following OASIS with follow up reported as 'postpartum'	No change in the number of symptomatic women following subsequent vaginal birth (n= 6) but worsening of symptoms in 3 women (1 women excluded as related to IBS (responded to treatment / normal RM & EAUS).
Walker, England, English, 2009, (87)	Cohort of women with previous OASIS and having a subsequent vaginal birth in a set time period identified by database, retrospective, consecutive	Impact of subsequent birth on previous OASIS	39	11, vaginal only	Unreported, outpatient clinic only	Unreported	Bowel function	Nov 2001-Nov 2007 , no initial survey but set time point survey at unreported time	Of women with subsequent vaginal birth 64% (7/11) had deterioration of EAUS/ARP findings. Only 1 woman developed AI symptoms (flatus incontinence)
Younis, England, English, 2010, (89)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, unreported	Impact of subsequent birth on previous OASIS	43	15, vaginal only	Unreported, outpatient clinic only	Unreported	Bowel function	Nov 2001-Nov 2007 , no initial survey but set time point survey at unreported time	Of women with subsequent vaginal birth 20% (3/15) developed AI symptoms (2 x flatus incontinence; 1 x faecal urgency)
Bondili, England, English, 2011, (88)	Cohort of women attending a specialist OASIS clinic, retrospective, consecutive	Impact of subsequent birth on previous OASIS	260	260, vaginal and caesarean section	Self-completed questionnaire , mixed outpatient clinic & verbal telephone interview for those who did not attend follow up appointment	Unreported	Bowel function	Jan 2004-Dec 2009, initial survey before 28 gestational weeks with follow up at 6-8 weeks postnatal	56/260 women (21.5%) were symptomatic following OASIS and underwent elective caesarean section for subsequent birth. At postnatal review there was an *improvement* in all AI symptom categories: Faecal urgency (39%; 18 vs 11; p=0.18) Faecal Incontinence (40%; 15 vs 9; p=0.21) Mixed symptoms (42%; 23

									vs 13; *p*=0.84) Symptomatic (43%; 56 vs 33; *p*=0.0012).
Dilmaghani-Tabriz, England, English, 2012, (85)	Cohort of women with OASIS and subsequent vaginal birth identified from hospital database, retrospective, consecutive	Impact of subsequent birth on previous OASIS	13	13, vaginal only	Self-completion questionnaire, postal only	Unreported	Bowel function	2007-2009, unreported	Flatus incontinence reported in two women (15.3%) after an average of 15 months post subsequent vaginal birth.

Meta-analysis of studies on incidence of worsening or de novo symptoms of AI in women with previous OASIS; subsequent vaginal birth versus subsequent caesarean section (Figure 2.7)

Tetzschner, Denmark, English, 1996, (86)	Cohort of women with previous OASIS attending specialist OASIS clinic, prospective, consecutive	Period follow up on primary OASIS	72	19, vaginal and caesarean section	Self-completion questionnaire, mixed outpatient clinic and postal	No	Bowel function	Unreported, initial survey at 1-3 months postnatal following OASIS with set time point survey at 2-4 years	Of women with subsequent vaginal birth (17/19), 4 (24%) had aggravation of AI symptoms (flatus incontinence)
Jordan, UK, English, 2015, (92)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, consecutive	Impact of subsequent birth on previous OASIS	137	137, vaginal and caesarean section	Self-completion questionnaire, outpatient clinic only	Yes, SMIS	Bowel function	Jan 2003 - Dec 2014, initial survey 28-32 gestational weeks of subsequent pregnancy with follow up survey at 12 weeks post subsequent birth	No significant change in SMIS scores for AI symptoms, for women with previous OASIS undergoing subsequent recommended vaginal birth (*p*=0.86) or caesarean section (*p*=0.46). However, worsening of SMIS QoL scores for women undergoing subsequent caesarean section (*p*=0.02), and

									significant worsening of AI symptoms in women having a vaginal birth and not recommended caesarean section (p<0.01)
Karmarkar, UK, English, 2015, (120)	Cohort of women with previous OASIS attending specialist OASIS clinic in subsequent pregnancy, prospective, consecutive	Impact of subsequent birth on previous OASIS	50	48, vaginal and caesarean section	Self-completion questionnaire, outpatient clinic only	Yes, unreported	Bowel function	Jan 2006 - Mar 2013, initial survey 8-12 weeks following OASIS, then seen in second trimester of subsequent pregnancy and at 8-12 weeks post subsequent birth	No worsening of AI symptoms in a/symptomatic women undergoing subsequent planned vaginal birth (n=26) and elective caesarean section (n=19), however, worsening of AI symptoms in symptomatic women achieving a non-planned vaginal birth (n=1) and emergency caesarean section (n=2)
Meta-analysis of studies on incidence of AI in women with previous OASIS/previous: ≥ 2 subsequent births versus 1 subsequent birth (Figure 2.4) **Meta- analysis of studies on incidence of AI in women with previous OASIS/previous 4th degree OASIS: ≥ 2 subsequent births versus 1 subsequent birth (Figure 2.5)**									
Sangalli, Switzerland, English, 2000, (75)	Cohort of women with OASIS in a set time period identified by database, retrospective, consecutive	Period follow up on primary OASIS	177	114, vaginal only	Self-completion questionnaire, postal only	No	Bowel function	01.01.82-31.12.83, no initial survey with set time point survey July -Dec 1995	Decrease in prevalence and no worsening of AI symptoms in women with previous 3rd degree OASIS undergoing a subsequent vaginal birth. However, for women with previous 4th degree OASIS, subsequent vaginal birth has an increased risk of severe incontinence (p=0.043).
Sze, USA, English, 2005, (74)	Cohort of women with OASIS (4th degree only)in a set time period identified by database,	Impact of subsequent birth on previous OASIS	148	96, vaginal only	Verbal Q&A interview, telephone only	No, 'questions were composed with terminology of Pescorati'	Bowel function, QoL	Jan 1984-Jun 2000, no initial survey but set time point survey varying with parity	Women with previous 4th degree OASIS who had ≥ 2 subsequent vaginal births, severity of AI symptoms (p=0.012) and severity of impact on daily QoL (p<0.001) were both

	retrospective, consecutive								significantly higher compared to women with 0 or 1 subsequent birth.
Sze, USA, English, 2005, (72)	Cohort of women with OASIS (3rd degree only) in a set time period identified by database, retrospective, consecutive	Impact of subsequent birth on previous OASIS & impact of another complete OASIS	211	141, vaginal only	Verbal interview , telephone only	No, 'questions were composed with terminology of Pescorati'	Bowel function, QoL	Jan 1984-Jun 1999, no initial survey but set time point survey varying with parity	Incidence of and severe symptoms of AI were similar in women with previous 3rd degree OASIS who had 0, 1 and ≥ 2 subsequent vaginal births (11/65, 11/67, 12/40, *p*=0.179; 2/65, 1/67, 2/40, *p*=0.811). Incidence of and severe symptoms of AI were similar in women with previous 3rd degree OASIS and no subsequent birth versus women with two OASIS and ≥ 2 subsequent vaginal births (11/65, 10/37, *p*=0.225; 2/65, 2/37, *p*=0.46)

Appendix 2.5 Excluded full-text articles from the systematic review with reason for exclusion

Primary reason for exclusion	Number of excluded articles	Studies
Population:		
Study did not concern women with previous OASIS	5	(1-5)
Intervention:		
Study did not provide data on women with previous OASIS and a subsequent birth	26	(6-31)
Outcome:		
No measure of QoL or Bowel function	14	(32-45)
Other:		
Review of published papers	3	(46-48)
Population included occult sphincter injuries	4	(49-52)
Inadequate / unable to extract data	11	(53-63)
Review of OASIS management	4	(64-67)
Paper on different topic	4	(68-71)
Study cohort duplicated in subsequent included paper	1	(72)

References of excluded full-text articles

1. Abbott D, Atere-Roberts N, Williams A, Oteng-Ntim E, Chappell LC. Obstetric anal sphincter injury. BMJ (Online). 2010;341(7764):140-5.
2. Dietz HP, Schierlitz L. Pelvic floor trauma in childbirth -- myth or reality? Australian & New Zealand Journal of Obstetrics & Gynaecology. 2005;45(1):3-12.
3. Geary M, Mellon C. Incidence of third-degree perineal tears in labour and outcome after primary repair. The British journal of surgery. 1996;83(7):1016-7.
4. MacKenzie R, Clubb A. Faecal incontinence following childbirth. Nursing times. 2007;103(14):40-1.
5. Naidoo K. Anal sphincter injury - An obstetric viewpoint. Clinical Risk. 2005;11(2):57-62.
6. Bharucha AE, Zinsmeister AR, Locke GR, Seide BM, McKeon K, Schleck CD, et al. Risk factors for fecal incontinence: A population-based study in women. American Journal of Gastroenterology. 2006;101(6):1305-12.
7. Bharucha AE, Fletcher JG, Melton LJ, 3rd, Zinsmeister AR. Obstetric trauma, pelvic floor injury and fecal incontinence: a population-based case-control study. American Journal of Gastroenterology. 2012;107(6):902-11.
8. Canavan L, Dinardo L. Mode of delivery following obstetric anal sphincter injury: An audit of practice in a UK district general hospital. BJOG: An International Journal of Obstetrics and Gynaecology. 2013;120.
9. Eason E, Labrecque M, Marcoux S, Mondor M. Anal incontinence after childbirth. CMAJ. 2002;166(3):326-30.
10. Eisenberg V, Avidan Y, Bitman G, Achiron R, Schiff E, Alcalay M. Obstetric anal sphincter tears grade 3a-are they as innocent as we think? Neurourology and Urodynamics. 2015;34:S177-S8.

11. Eogan M, O'Herlihy C. Diagnosis and management of obstetric anal sphincter injury. Current Opinion in Obstetrics & Gynecology. 2006;18(2):141-7.
12. Farrell SA, Flowerdew G, Gilmour D, Turnbull GK, Schmidt MH, Baskett TF, et al. Overlapping Compared With End-to-End Repair of Complete Third-Degree or Fourth-Degree Obstetric Tears: Three-Year Follow-up of a Randomized Controlled Trial. Obstetrics & Gynecology. 2012;120(4):803-9.
13. Fitzpatrick M, O'Herlihy C. Short-term and long-term effects of obstetric anal sphincter injury and their management. Current Opinion in Obstetrics & Gynecology. 2005;17(6):605-11.
14. Nazir M, Stien R, Carlsen E, Jacobsen AF, Nesheim BI. Early evaluation of bowel symptoms after primary repair of obstetric perineal rupture is misleading: an observational cohort study. Diseases of the Colon & Rectum. 2003;46(9):1245-50.
15. Luthander C, Emilsson T, Ljunggren G, Hammarstrom M. A questionnaire on pelvic floor dysfunction postpartum. International Urogynecology Journal. 2011;22(1):105-13.
16. Lacross A, Groff M, Smaldone A. Obstetric anal sphincter injury and anal incontinence following vaginal birth: A systematic review and meta-analysis. Journal of Midwifery and Women's Health. 2015;60(1):37-47.
17. Kumar R, Ooi C, Nicoll A. Five year follow-up of women with obstetric anal sphincter injury. Journal of Obstetrics and Gynaecology. 2010;30(1).
18. Jordan P, Horrocks E, Burgell R, Scott M, Chaliha C, Knowles C. Co-existing faecal incontinence and rectal evacuatory disorder following childbirth: An under-reported phenomenon. BJOG: An International Journal of Obstetrics and Gynaecology. 2013;120.
19. Imran R, Izzat HN. The outcome of primary repair in third and fourth degree perineal tears. BJOG: An International Journal of Obstetrics and Gynaecology. 2012;119.
20. Nordenstam J, Mellgren A, Altman D, López A, Johansson C, Anzén B, et al. Immediate or delayed repair of obstetric anal sphincter tears-a randomised controlled trial. BJOG: An International Journal of Obstetrics & Gynaecology. 2008;115(7):857-66.
21. Norderval S, Nsubuga D, Bjelke C, Frasunek J, Myklebust I, Vonen B. Anal incontinence after obstetric sphincter tears: incidence in a Norwegian county. Acta Obstetricia et Gynecologica Scandinavica. 2004;83(10):989-94.
22. Radestad I, Olsson A, Nissen E, Rubertsson C. Tears in the vagina, perineum, sphincter ani, and rectum and first sexual intercourse after childbirth: a nationwide follow-up. Birth. 2008;35(2):98-106.
23. Rogers RG, Borders N, Leeman LM, Albers LL. Does spontaneous genital tract trauma impact postpartum sexual function? Journal of Midwifery & Women's Health. 2009;54(2):98-104.
24. Shek KL, Guzman R, Dietz HP. Residual defects of the external anal sphincter are common after oasis repair. Neurourology and Urodynamics. 2012;31(6):913-4.
25. Signorello LB, Harlow BL, Chekos AK, Repke JT. Postpartum sexual functioning and its relationship to perineal trauma: a retrospective cohort study of primiparous women. American Journal of Obstetrics & Gynecology. 2001;184(5):881-8; discussion 8-90.

26. Fritel X, Khoshnood B, Fauconnier A. Four years after first delivery, do urinary incontinence and anal incontinence share same obstetrical risk factors? Neurourology and Urodynamics. 2009;28(7):902-3.
27. Gjessing H, Backe B, Sahlin Y. Third degree obstetric tears; outcome after primary repair. Acta Obstetricia et Gynecologica Scandinavica. 1998;77(7):736-40.
28. Rasmussen JL, Ringsberg KC. Being involved in an everlasting fight -- a life with postnatal faecal incontinence. A qualitative study. Scandinavian Journal of Caring Sciences. 2010;24(1):108-16.
29. Visscher AP, Lam TJ, Hart NA, Mulder CJ, Felt-Bersma RJ. Anal incontinence, sexual complaints, and anorectal function in patients with a third degree anal sphincter rupture: Long-term follow-up. Gastroenterology. 2013;144(5 SUPPL. 1).
30. Bavananthan T, Shahid J. Follow-up of third and fourth degree tears and management of subsequent pregnancy. BJOG: An International Journal of Obstetrics and Gynaecology. 2013;120:177-8.
31. Fitzpatrick M, Fynes M, Cassidy M, Behan M, O'Connell PR, O'Herlihy C. Prospective study of the influence of parity and operative technique on the outcome of primary anal sphincter repair following obstetrical injury. European Journal of Obstetrics Gynecology and Reproductive Biology. 2000;89(2):159-63.
32. Ali A, Glennon K, Kirkham C, Yousif S, Eogan M. Delivery outcomes and events in subsequent pregnancies after previous anal sphincter injury. European Journal of Obstetrics Gynecology and Reproductive Biology. 2014;174(1):51-3.
33. Bagade P, Mackenzie S. The long-term outcome of third and fourth degree perineal tears. International Journal of Gynecology and Obstetrics. 2009;107.
34. Bagade P, MacKenzie S. Outcomes from medium term follow-up of patients with third and fourth degree perineal tears. Journal of Obstetrics and Gynaecology. 2010;30(6):609-12.
35. Basham E, Stock L, Lewicky-Gaupp C, Mitchell C, Gossett DR. Subsequent pregnancy Outcomes After Obstetric Anal Sphincter Injuries (OASIS). Obstetrical and Gynecological Survey. 2014;69(2):78-9.
36. Boggs EW, Berger H, Urquia M, McDermott C. Mode of delivery following obstetric anal sphincter injury. International Urogynecology Journal and Pelvic Floor Dysfunction. 2013;24:S30-S1.
37. Boij C, Matthiesen L, Krantz M, Boij R. Sexual function and wellbeing after obstetric and sphinter [sic] injury. British Journal of Midwifery. 2007;15(11):684-9.
38. Eddama M, Totton L, Vasudevan SP, Motson R. In women who sustained a third degree perineal tear, can we predict further tears in their subsequent deliveries? Colorectal Disease. 2012;14.
39. Thiel M, Behrens R. Outcome of subsequent delivery in women with previous obstetric anal sphincter injury (OASIS). International Urogynecology Journal and Pelvic Floor Dysfunction. 2015;1):S129-S30.
40. Ononeze BO, Gleeson N, Turner MJ. Management of third degree perineal tear and choice of mode of delivery in subsequent pregnancies. Journal of Obstetrics and Gynaecology. 2004;24(2):148-51.
41. Soerensen MM, Buntzen S, Bek KM, Laurberg S. Complete obstetric anal sphincter tear and risk of long-term fecal incontinence: a cohort study. Diseases of the Colon & Rectum. 2013;56(8):992-1001.

42. Raisanen S, Vehvilainen-Julkunen K, Cartwright R, Gissler M, Heinonen S. A prior cesarean section and incidence of obstetric anal sphincter injury. International Urogynecology Journal. 2013;24(8):1331-9.
43. Davies D, Bahl R. Recurrence rate of third degree perineal tears at St Michael's Hospital. Archives of Disease in Childhood: Fetal and Neonatal Edition. 2013;98((Suppl 1)):A1-A112.
44. Mahony R, O'Herlihy C. Recent impact of anal sphincter injury on overall Caesarean section incidence. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2006;46(3):202-4.
45. Doumouchtsis S, Anparasan A, Chis Ster I, Abbas N, Gauthaman N. Recurrent Obstetric Anal Sphincter Injuries (OASIS): Is prediction Possible? Age. 2014;1:0.66.
46. Abed H, Rogers R. Managing future pregnancies after a severe perineal laceration. Contemporary OB/GYN. 2006;51(5):34-41.
47. Fischer JR. What is new in obstetric anal sphincter injuries?: Best articles from the past year. Obstetrics and Gynecology. 2013;122(1):154-5.
48. Fowler GE. Risk factors for and management of obstetric anal sphincter injury. Obstetrics, Gynaecology and Reproductive Medicine. 2013;23(5):131-6.
49. Bollard RC, Gardiner A, Duthie GS, Lindow SW. Anal sphincter injury, fecal and urinary incontinence: a 34-year follow-up after forceps delivery. Diseases of the Colon & Rectum. 2003;46(8):1083-8.
50. Faltin DL, Sangalli MR, Roche B, Floris L, Boulvain M, Weil A. Does a second delivery increase the risk of anal incontinence? BJOG: An International Journal of Obstetrics & Gynaecology. 2001;108(7):684-8.
51. Fynes M, Donnelly V, Behan M, O'Connell PR, O'Herlihy C. Effect of second vaginal delivery on anorectal physiology and faecal continence: a prospective study. Lancet. 1999;354(9183):983-6.
52. Frudinger A, Ballon M, Taylor SA, Halligan S. The natural history of clinically unrecognized anal sphincter tears over 10 years after first vaginal delivery. Obstetrics and Gynecology. 2008;111(5):1058-64.
53. Daly O, Sultan A, Thakar R. Previous obstetric anal sphincter injury: Is vaginal delivery a good option for women with a low risk of Anorectal dysfunction? Australian and New Zealand Journal of Obstetrics and Gynaecology. 2012;52(6):599-600.
54. Fitzpatrick M, Cassidy M, Barussaud M, Hehir M, O'Herlihy C. Does anal sphincter injury preclude subsequent vaginal delivery? International Urogynecology Journal and Pelvic Floor Dysfunction. 2013;24:S70-S1.
55. Williams A, Lavender T, Richmond DH, Tincello DG. Women's experiences after a third-degree obstetric anal sphincter tear: a qualitative study. Birth: Issues in Perinatal Care. 2005;32(2):129-37.
56. Fritel X, Ringa V, Varnoux N, Zins M, Breart G. Mode of delivery and fecal incontinence at midlife: A study of 2,640 women in the Gazel cohort. Obstetrics and Gynecology. 2007;110(1):31-8.
57. Fritel X, Khoshnood B, Fauconnier A. Specific obstetrical risk factors for urinary versus anal incontinence 4years after first delivery. Progres en Urologie. 2013;23(11):911-6.
58. Fornell EU, Matthiesen L, Sjodahl R, Berg G. Obstetric anal sphincter injury ten years after: subjective and objective long-term effects. BJOG: An International Journal of Obstetrics & Gynaecology. 2005;112(3):312-6.

59. Mous M, Muller SA, de JWJ. Long-term effects of anal sphincter rupture during vaginal delivery: faecal incontinence and sexual complaints. BJOG: An International Journal of Obstetrics & Gynaecology. 2008;115(2):234-9.
60. Nygaard IE, Rao SS, Dawson JD. Anal incontinence after anal sphincter disruption: a 30-year retrospective cohort study. Obstetrics & Gynecology. 1997;89(6):896-901.
61. Palm A, Israelsson L, Bolin M, Danielsson I. Symptoms after obstetric sphincter injuries have little effect on quality of life. Acta Obstetricia et Gynecologica Scandinavica. 2013;92(1):109-15.
62. Samarasekera DN, Bekhit MT, Wright Y, Lowndes RH, Stanley KP, Preston JP, et al. Long-term anal continence and quality of life following postpartum anal sphincter injury. Colorectal Disease. 2008;10(8):793-9.
63. Yousif S, Eogan M. Mode of delivery after previus anal sphincter injury (ASI): Role of the perineal clinic. Irish Journal of Medical Science. 2011;180.
64. Fernando RJ, Sultan AH, Radley S, Jones PW, Johanson RB. Management of obstetric anal sphincter injury: a systematic review & national practice survey. BMC health services research. 2002;2(1).
65. Fernando RJ. Risk factors and management of obstetric perineal injury. Obstetrics, Gynaecology and Reproductive Medicine. 2007;17(8):238-43.
66. Fitzpatrick M, O'Herlihy C. The effects of labour and delivery on the pelvic floor. Best Practice and Research: Clinical Obstetrics and Gynaecology. 2001;15(1):63-79.
67. Fitzpatrick M, O'Herlihy C. Vaginal birth and perineal trauma. Current Opinion in Obstetrics and Gynecology. 2000;12(6):487-90.
68. Cockell SJ, Oates-Johnson T, Gilmour DT, Vallis TM, Turnbull GK. Postpartum flatal and fecal incontinence quality-of-life scale: a disease- and population-specific measure. Qualitative Health Research. 2003;13(8):1132-45.
69. Laine K, Skjeldestad FE, Sandvik L, Staff AC. Prevalence and risk indicators for anal incontinence among pregnant women. ISRN Obstetrics and Gynecology. 2013;2013.
70. Zorcolo L, Covotta L, Bartolo DC. Outcome of anterior sphincter repair for obstetric injury: comparison of early and late results. Diseases of the colon and rectum. 2005;48(3):524-31.
71. Haadem K, Gudmundsson S. Can women with intrapartum rupture of anal sphincter still suffer after-effects two decades later? Acta Obstetricia et Gynecologica Scandinavica. 1997;76(6):601-3.
72. Pollack J, Nordenstam J, Brismar S, Lopez A, Altman D, Zetterstrom J. Anal incontinence after vaginal delivery: A five-year prospective cohort study. Obstetrics and Gynecology. 2004;104(6):1397-402.

Appendix 3.1 Postal Questionnaire

Birmingham Women's NHS
NHS Foundation Trust

Long-term effect of obstetric anal sphincter injury on quality of life & bowel function - Questionnaire

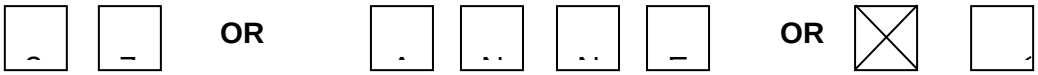
CONFIDENTIAL

If you would like any further information or have queries about the study, please contact:

Sara Webb
[redacted]

HOW TO FILL IN THIS QUESTIONNAIRE

Most questions can be answered by putting numbers or a cross/tick in the appropriate box or boxes. Please print your answers carefully within the boxes like this

eg  **OR** **OR**

Section A is about any bowel problems you may have and how much they affect you.

Section B asks you about each of the births you have had.

Section C is about you and your consent for participation in the study.

Thank you for your time in completing this questionnaire.

Your answers will be treated with complete confidentiality and will only be used for research aimed at improving future care for women, like yourself, who have experienced an obstetric anal sphincter injury.

SECTION A: Many women who have had a baby have bowel problems and we would like to know what your bowel problems are and how much they affect you. We would be grateful if you could answer the following questions, thinking about how you have been, on average, over the past four weeks.

		Very good	Good	Fair	Poor	Very Poor
A1	How would you describe your health at the present?	☐	☐	☐	☐	☐
		Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
A2	How much do you think your bowel problem affects your life?	☐	☐	☐	☐	☐
		Never	**Occasionally**	**Sometimes**	**Most of the time**	**All of the time**
A3	How often do you have a strong desire to move your bowel which makes you rush to the toilet?	☐	☐	☐	☐	☐
A4	How often do your bowels leak when coughing or sneezing?	☐	☐	☐	☐	☐
A5	How often do your bowels leak when walking?	☐	☐	☐	☐	☐
A6	Do your bowels leak during the rest of the day or night?	☐	☐	☐	☐	☐
A7	Do you have difficulty wiping clean after you have opened your bowels?	☐	☐	☐	☐	☐
A8	Do you have difficulty controlling wind?	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐

A9	Is the leakage from your bowels loose?	☐	☐	☐	☐	☐
A10	Is the leakage from your bowels solid?	☐	☐	☐	☐	☐
A11	Do your bowels leak during or after sexual intercourse?	☐	☐	☐	☐	☐

If this question is not applicable to you is it because:

A11a ☐ the bowel problem makes intercourse impossible ☐ you are not in a sexual relationship

		Not every day	1-2 times	3-4 times	5-6 times	7 or more times
A12	How often do you move your bowels every day?	☐	☐	☐	☐	☐

We would like to know how any bowel problem you have previously described affect your daily working, social and home life.

		Never	Rarely	Sometimes	Often	Always
A13	Does your bowel problem affect you doing the jobs within the home?	☐	☐	☐	☐	☐
A14	Does your bowel problem affect your job, or your normal daily activities outside the home?	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐

A15	Does your bowel problem affect your ability to travel?	☐	☐	☐	☐	☐
A16	Does your bowel problem affect your physical activities (eg, going for a walk, running, sport, gym, etc)?	☐	☐	☐	☐	☐
A17	Does your bowel problem limit your social life?	☐	☐	☐	☐	☐
A18	Does your bowel problem limit your ability to see and visit friends?	☐	☐	☐	☐	☐

We would like to know how any bowel problems you have affect your personal relationships. If any of these questions are not applicable then please leave them blank

		Never	Rarely	Sometimes	Often	Always
A19	Does your bowel problem affect your relationship with your partner?	☐	☐	☐	☐	☐
A20	Does your bowel problem affect your sex life?	☐	☐	☐	☐	☐
A21	Does your bowel problem affect your family life?	☐	☐	☐	☐	☐

We would like to know how any bowel problems you have affect you emotionally.

		Never	Rarely	Sometimes	Often	Always
A22	Does your bowel problem make you feel depressed?	☐	☐	☐	☐	☐
A23	Does your bowel problem make you feel anxious or nervous?	☐	☐	☐	☐	☐
A24	Does your bowel problem make you feel bad about yourself?	☐	☐	☐	☐	☐

We would like to know how any bowel problems you have affect you emotionally.

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

A25	Does your bowel problem affect your sleep?	☐	☐	☐	☐	☐
A26	Does your bowel problem make you feel worn out and tired?	☐	☐	☐	☐	☐

We would like to know how any bowel problems you have affect your lifestyle. Do you do any of the following and if so, how much?

		Never	Rarely	Sometimes	Often	Always
A27	Wear pads to keep clean?	☐	☐	☐	☐	☐
A28	Be careful how much food you eat?	☐	☐	☐	☐	☐
A29	Change your underclothes because they get dirty?	☐	☐	☐	☐	☐
A30	Worry in case you smell?	☐	☐	☐	☐	☐
A31	Get embarrassed because of your bowel problem?	☐	☐	☐	☐	☐

SECTION B: Please could you tell us a little about all of the births you have had? If there were twins or more, please fill in the next BIRTH record for the second and subsequent babies.

B1 FIRST BIRTH **D D** **M M** **Y Y Y Y**

B1a Date of baby's birth ☐☐ ☐☐ ☐☐☐☐

B1b Baby's birth weight ☐☐ lbs ☐☐ oz **OR** ☐☐☐☐ kg ☐ Don't know

B1c What type of delivery did you have? Normal vaginal delivery ☐ Caesarean before labour ☐ Caesarean during labour ☐

Vacuum delivery ☐ Forceps delivery ☐ Breech (vaginal) ☐

B1d Did you have stitches to your perineum (tail end)?

Stitches to cut ☐ Stitches to tear ☐ Tear but no stitches ☐ No stitches, no tear ☐

B1e Did the tear extend into the muscle around your back passage (obstetric anal sphincter injury)? Yes ☐ No ☐ Don't know ☐

B1f Was it a single or multiple birth (eg twins)? Single ☐ Multiple ☐

B1g Did you have an epidural or spinal anaesthetic for this birth? Yes ☐ No ☐

SECOND BIRTH **D D** **M M** **Y Y Y Y**

B2a Date of baby's birth ☐☐ ☐☐ ☐☐☐☐

B2b Baby's birth weight ☐☐ lbs ☐☐ oz **OR** ☐☐☐☐ kg Don't know ☐

B2c What type of delivery did you have? Normal vaginal delivery ☐ Caesarean before labour ☐ Caesarean during labour ☐

Vacuum delivery ☐ Forceps delivery ☐ Breech (vaginal) ☐

B2d Did you have stitches to your perineum (tail end)?

Stitches to cut ☐ Stitches to tear ☐ Tear but no stitches ☐ No stitches, no tear ☐

B2e Did the tear extend into the muscle around your back passage (obstetric anal sphincter injury)? Yes ☐ No ☐ Don't know ☐

B2f Was it a single or multiple birth (eg twins)? Single ☐ Multiple ☐ B2g Did you have an epidural or spinal anaesthetic? Yes ☐ No ☐

B3 THIRD BIRTH **D D** **M M** **Y Y Y Y**

B3a Date of baby's birth ☐☐ ☐☐ ☐☐☐☐

B3b Baby's birth weight ☐☐ lbs ☐☐ oz **OR** ☐☐☐☐ kg Don't know ☐

B3c What type of delivery did you have? Normal vaginal delivery ☐ Caesarean before labour ☐ Caesarean during labour ☐

Vacuum delivery ☐ Forceps delivery ☐ Breech (vaginal) ☐

B3d Did you have stitches to your perineum (tail end)?

Stitches to cut ☐ Stitches to tear ☐ Tear but no stitches ☐ No stitches, no tear ☐

B3e Did the tear extend into the muscle around your back passage (obstetric anal sphincter injury)? Yes ☐ No ☐ Don't know ☐

B3f Was it a single or multiple birth (eg twins)? Single ☐ Multiple B3g Did you have an epidural or spinal anaesthetic? Yes No ☐

B5 FOURTH BIRTH **D D** **M M** **Y Y Y Y**

B5a Date of baby's birth ☐☐ ☐☐ ☐☐☐☐

B5b Baby's birth weight ☐☐ lbs ☐☐ oz **OR** ☐☐☐☐ kg Don't know ☐

B5c What type of delivery did you have? Normal vaginal delivery ☐ Caesarean before labour ☐ Caesarean during labour ☐

Vacuum delivery ☐ Forceps delivery ☐ Breech (vaginal) ☐

B5d Did you have stitches to your perineum (tail end)?

Stitches to cut ☐ Stitches to tear ☐ Tear but no stitches ☐ No stitches, no tear ☐

B5e Did the tear extend into the muscle around your back passage (obstetric anal sphincter injury)? Yes ☐ No ☐ Don't know ☐

B5f Was it a single or multiple birth (eg twins)? Single ☐ Multiple ☐ B5g Did you have an epidural or spinal anaesthetic? Yes ☐ No ☐

B5 FIFTH BIRTH **D D** **M M** **Y Y Y Y**

B5a Date of baby's birth ☐☐ ☐☐ ☐☐☐☐

B5b Baby's birth weight ☐☐ lbs ☐☐ oz **OR** ☐☐☐☐ kg Don't know ☐

B4c What type of delivery did you have? Normal vaginal delivery ☐ Caesarean before labour ☐ Caesarean during labour ☐

Vacuum delivery ☐ Forceps delivery ☐ Breech (vaginal) ☐

B4d Did you have stitches to your perineum (tail end)?

Stitches to cut ☐ Stitches to tear ☐ Tear but no stitches ☐ No stitches, no tear ☐

B4e Did the tear extend into the muscle around your back passage (obstetric anal sphincter injury)? Yes ☐ No ☐ Don't know ☐

B4f Was it a single or multiple birth (eg twins)? Single ☐ Multiple ☐ B4g Did you have an epidural or spinal anaesthetic? Yes ☐ No ☐

B5 SIXTH BIRTH **D D** **M M** **Y Y Y Y**

B5a Date of baby's birth ☐☐ ☐☐ ☐☐☐☐

B5b Baby's birth weight ☐☐ lbs ☐☐ oz **OR** ☐☐☐☐ kg Don't know ☐

B5c What type of delivery did you have? Normal vaginal delivery ☐ Caesarean before labour ☐ Caesarean during labour ☐

Vacuum delivery ☐ Forceps delivery ☐ Breech (vaginal) ☐

B5d Did you have stitches to your perineum (tail end)?

Stitches to cut ☐ Stitches to tear ☐ Tear but no stitches ☐ No stitches, no tear ☐

B5e Did the tear extend into the muscle around your back passage (obstetric anal sphincter injury)? Yes ☐ No ☐ Don't know ☐

B5f Was it a single or multiple birth (eg twins)? Single ☐ Multiple ☐ B5g Did you have an epidural or spinal anaesthetic? Yes ☐ No ☐

F7 If you have had more than 6 babies how many in total have you had? ☐☐

F8 Are you pregnant at the moment? Yes ☐ No ☐

If YES, date baby is due **D D** ☐☐ **M M** ☐☐ **Y Y Y Y** ☐☐☐☐

SECTION C:

		D D	M M	Y Y Y Y
C1	Date Questionnaire filled in			
C2	Your date of birth			

C3 Which ethnic group do you belong to? Cross the box that applies to you:

British	☐	Indian	☐
Irish	☐	Pakistani	☐
Other White	☐	Bangladeshi	☐
		Other Asian	☐
White & Black Caribbean	☐		
White & Black African	☐	Black Caribbean	☐
White & Asian	☐	Black African	☐
Other Mixed	☐	Other Black	☐
Chinese	☐	Other Ethnic Group	☐

C4 May we access your hospital notes for any further relevant information?
Yes ☐ No ☐

C5 Would you like to be notified of the results of the study? Yes ☐ No ☐

C6 Please tick to accept that your GP will be notified that you are taking part in this postal study – this is standard, good research practice: ☐

Thank you very much for your help

Your answers will be treated with complete confidentiality and will only be used for research aimed at improving future care for women, like yourself, who have experienced an obstetric anal sphincter injury.

Please send the questionnaire back to us in the postage paid envelope provided

Appendix 3.2 Multivariate analysis of short-term bowel function, maternal intrapartum, OASIS and neonatal characteristics on long-term bowel function – respondents post 2002

Characteristic (n/289)		Bowel symptoms at questionnaire completion: Mean 5.33 years (±2.59)											
		Poor control of flatus			Faecal urgency			Faecal Leakage – Any[≠]			Faecal Leakage – Passive only		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at initial hospital clinic review													
Faecal urgency													
Never	(219)		Reference			Reference			Reference			Reference	
Sometimes	(41)	2.20	0.83-5.88	0.115	3.92	1.21-12.67	*0.023*	4.95	1.49-16.44	*0.009*	1.77	0.81-3.88	0.151
Frequently	(29)	0.28	0.83-9.61	0.098	5.51	1.11-27.47	*0.037*	3.29	0.73-14.95	0.123	1.57	0.60-4.08	0.358
Control of flatus													
Good	(231)		Reference			Reference			Reference			Reference	
Variable	(45)	7.08	2.28-21.98	*0.001*	1.57	0.57-4.33	0.381	0.55	0.13-2.27	0.409	0.64	0.29-1.39	0.258
Poor	(13)	4.29	0.48-38.20	0.191	0.52	0.09-3.09	0.475	1.17	0.18-7.72	0.870	1.72	0.47-6.31	0.413
Maternal characteristics													
Age at OASIS		1.04	0.98-1.10	0.255	1.00	0.94-1.07	0.945	1.01	0.92-1.11	0.819	1.01	0.96-1.07	0.703
Years between OASIS and questionnaire completion		1.04	0.89-1.21	0.603	0.93	0.78-1.10	0.390	1.18	0.93-1.49	0.165	1.05	0.91-1.22	0.485
Parity (all birth modes)													
1	(90)		Reference			Reference			Reference			Reference	
2	(152)	1.70	0.51-5.65	0.387	0.75	0.22-2.57	0.644	0.12	0.01-1.14	0.066	1.02	0.40-2.59	0.968
≥ 3	(47)	2.77	0.65-11.75	0.167	1.02	0.23-4.52	0.980	0.19	0.02-2.30	0.191	1.27	0.39-4.15	0.695
Post-OASIS births													

None	(120)										Reference	
Vaginal [¥]	(106)	0.41	0.12-1.37	0.148	0.51	0.15-1.70	0.274	3.48	0.32-37.46	0.304	0.68	0.26-1.82	0.447
Caesarean section only	(63)	0.23	0.06-0.80	*0.021*	0.45	0.13-1.56	0.209	1.80	0.15-21.65	0.643	0.34	0.11-0.98	*0.046*
Intrapartum characteristics													
OASIS birth mode													
SVD	(183)		Reference			Reference			Reference			Reference	
Kiwi	(22)	0.60	0.21-1.67	0.318	4.42	0.42-4.81	0.575	1.11	0.21-5.83	0.906	2.86	1.09-7.50	*0.033*
Low/unspecified forceps	(53)	1.88	0.85-4.13	0.119	1.91	0.77-4.70	0.161	0.60	0.17-2.17	0.433	1.25	0.62-2.52	0.539
Rotational forceps	(30)	0.55	0.20-1.48	0.235	0.35	0.12-1.06	0.063	1.11	0.23-5.30	0.895	1.65	0.65-4.22	0.292
OASIS characteristics													
OASIS classification													
3A	(110)		Reference			Reference			Reference			Reference	
3B	(109)	1.41	0.74-2.69	0.293	2.13	1.04-4.36	*0.039*	0.93	0.30-2.89	0.904	0.68	0.36-1.28	0.236
3C/4	(51)	1.32	0.59-2.98	0.504	1.75	0.72-4.28	0.220	1.30	0.34-5.04	0.703	1.07	0.49-2.31	0.868
Unspecified	(19)	2.87	0.74-11.18	0.129	1.13	0.30-4.26	0.861	2.19	0.35-13.86	0.470	1.53	0.46-5.07	0.485
OASIS repair method													
End-to-end	(105)		Reference			Reference			Reference			Reference	
Overlap	(92)	1.23	0.61-2.49	0.565	1.27	0.59-2.71	0.546	0.76	0.23-2.48	0.647	0.89	0.46-1.72	0.722
Unspecified	(92)	1.33	0.61-2.93	0.474	2.24	0.93-5.38	0.072	0.75	0.18-3.15	0.689	0.74	0.33-1.65	0.456
Neonatal characteristics													
Birthweight		1.00	(1.00-1.00)	0.820	1.00	(1.00-1.00)	0.094	1.00	(1.00-1.00)	0.435	1.00	(1.00-1.00)	0.734

Appendix 3.3 Multivariate analysis of short-term bowel function, maternal, intrapartum, OASIS and neonatal characteristics on long-term QoL – respondents post 2002

Characteristic (n/289)		MHQ QoL domain								
		General Health Perception			Incontinence Impact			Role Limitations		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at initial hospital clinic review										
Faecal urgency										
Never	(219)		Reference			Reference			Reference	
Sometimes	(41)	2.09	(0.86-5.06)	0.104	2.49	(1.09-5.68)	*0.030*	0.96	(0.41-2.72)	0.929
Frequently	(29)	0.65	(0.26-1.65)	0.366	2.99	(1.06-8.48)	*0.039*	1.93	(0.58-6.41)	*0.284*
Flatus control										
Good	(231)		Reference			Reference			Reference	
Variable	(45)	0.92	(0.43-1.97)	0.833	0.97	(0.46-2.04)	0.940	0.97	(0.42-2.20)	0.932
Poor	(13)	1.14	(0.28-4.59)	0.859	2.38	(0.44-12.90)	0.313	3.20	(0.36-28.49)	0.298
Maternal characteristics										
Age at OASIS		0.97	(0.92-1.02)	0.231	0.97	(0.92-1.02)	0.254	1.02	(0.96-1.08)	0.536
Years between OASIS and questionnaire completion		1.16	(1.00-1.34)	*0.037*	0.96	(0.84-1.11)	0.589	1.06	(0.91-1.25)	0.452
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(152)	2.42	(0.78-7.47)	0.124	1.34	(0.49-3.62)	0.570	1.14	(0.36-3.50)	0.826
≥ 3	(47)	2.39	(0.63-9.00)	0.199	1.23	(0.36-4.18)	0.741	0.93	(0.24-3.67)	0.915
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal ¥	(106)	0.35	(0.11-1.24)	0.081	0.62	(0.23-1.72)	0.361	0.83	(0.27-2.60)	0.748

Caesarean section only	(63)	0.19	(0.06-0.61)	*0.006*	0.52	(0.18-1.48)	0.216	0.80	(0.24-2.62)	0.706
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(22)	1.01	(0.38-2.68)	0.982	2.09	(0.74-5.93)	0.164	1.06	(0.35-3.26)	0.918
Low/unspecified forceps	(53)	1.46	(0.72-2.95)	0.297	1.12	(0.57-2.21)	0.753	0.86	(0.40-1.84)	0.692
Rotational forceps	(30)	1.59	(0.61-4.14)	0.344	0.62	(0.25-1.58)	0.316	0.60	(0.22-1.60)	0.305
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(109)	1.11	(0.60-2.07)	0.738	1.05	(0.58-1.92)	0.869	1.35	(0.71-2.58)	0.358
3C/4	(51)	1.01	(0.47-2.14)	0.990	0.86	(0.41-1.81)	0.684	4.29	(1.49-12.33)	*0.007*
Unspecified	(19)	0.97	(0.30-3.13)	0.960	1.15	(0.35-3.72)	0.823	1.69	(0.44-6.53)	0.444
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.85	(0.43-1.65)	0.626	0.65	(0.34-1.24)	0.189	0.89	(0.44-1.83)	0.757
Unspecified	(92)	0.49	(0.23-1.06)	0.069	1.22	(0.58-2.59)	0.603	0.90	(0.39-2.10)	0.812
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.922	1.00	(1.00-1.00)	0.890	1.00	(1.00-1.00)	0.452

Characteristic (n)		**Physical Limitations**			**Social Limitations**			**Physical Limitations**		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at initial hospital review										
Faecal urgency										
None	(219)		Reference			Reference			Reference	
Sometimes	(41)	2.64	(1.15-6.02)	*0.022*	3.84	(1.60-9.22)	*0.003*	1.51	(0.61-3.75)	0.373
Frequently	(29)	1.91	(0.73-5.02)	0.188	2.71	(0.96-7.66)	0.060	1.43	(0.45-4.62)	0.546
Flatus control										
Good	(231)		Reference			Reference			Reference	

Variable	(45)	0.61	(0.26-1.42)	0.250	0.77	(0.30-1.96)	0.583	0.84	(0.34-2.08)	0.702
Poor	(13)	2.12	(0.56-7.98)	0.266	2.37	(0.62-9.03)	0.205	3.28	(0.85-12.76)	0.086
Maternal characteristics										
Age at OASIS		0.98	(0.92-1.04)	0.517	0.99	(0.92-1.06)	0.759	0.99	(0.93-1.06)	0.783
Years between OASIS and questionnaire completion		0.91	(0.79-1.06)	0.245	0.99	(0.84-1.17)	0.877	0.87	(0.73-1.03)	0.096
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(152)	1.55	(0.57-4.19)	0.391	2.25	(0.77-6.60)	0.139	2.10	(0.74-5.91)	0.162
≥ 3	(47)	2.09	(0.59-7.44)	0.257	2.93	(0.74-11.58)	0.125	1.76	(0.45-6.87)	0.416
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal ¥	(106)	0.45	(0.15-1.30)	0.139	0.43	(0.14-1.34)	0.144	0.67	(0.23-1.98)	0.470
Caesarean section only	(63)	0.53	(0.18-1.60)	0.261	0.47	(0.14-1.54)	0.212	0.31	(0.09-1.06)	0.061
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(22)	2.22	(0.82-6.02)	0.118	1.57	(0.50-4.94)	0.444	1.16	(0.39-3.48)	0.785
Low/unspecified forceps	(53)	1.29	(0.62-2.70)	0.497	0.88	(0.38-2.03)	0.754	0.51	(0.20-1.27)	0.148
Rotational forceps	(30)	0.57	(0.19-1.71)	0.315	0.45	(0.11-1.80)	0.259	0.40	(0.12-1.36)	0.141
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(109)	1.19	(0.59-2.38)	0.628	1.15	(0.53-2.52)	0.719	1.08	(0.51-2.33)	0.836
3C/4	(51)	1.22	(0.52-2.90)	0.644	1.23	(0.47-2.22)	0.670	1.50	(0.61-3.67)	0.379
Unspecified	(19)	2.54	(0.75-8.63)	0.136	1.65	(0.42-6.45)	0.474	5.11	(1.33-16.64)	*0.017*
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.52	(0.24-1.10)	0.087	0.85	(0.37-1.98)	0.713	0.71	(0.32-1.57)	0.394

Unspecified	(92)	1.06	(0.45-2.47)	0.896	1.22	(0.46-3.22)	0.692	1.09	(0.43-2.74)	0.857
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.682	1.00	(1.00-1.00)	0.193	1.00	(1.00-1.00)	0.856
Characteristic (n)		**Emotions**			**Sleep/Energy**			**Emotions**		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at initial hospital review										
Faecal urgency										
None	(219)		Reference			Reference			Reference	
Sometimes	(41)	1.23	(0.56-2.72)	0.607	1.60	(0.66-3.89)	0.297	1.78	(0.81-3.89)	0.150
Frequently	(29)	1.11	(0.44-2.82)	0.820	1.35	(0.45-4.06)	0.591	0.78	(0.31-1.96)	0.594
Flatus control										
Good	(231)		Reference			Reference			Reference	
Variable	(45)	1.15	(0.56-2.36)	0.712	0.80	(0.33-1.97)	0.629	1.21	(0.59-2.47)	0.601
Poor	(13)	6.22	(1.22-31.81)	*0.028*	1.23	(0.29-5.12)	0.779	4.16	(0.81-21.43)	0.088
Maternal characteristics										
Age at OASIS		0.99	(0.93-1.04)	0.567	0.96	(0.90-1.02)	0.139	1.01	(0.96-1.06)	0.778
Years between OASIS and questionnaire completion		1.08	(0.94-1.23)	0.298	1.01	(0.87-1.19)	0.873	1.03	(0.90-1.18)	0.658
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(152)	1.03	(0.40-2.65)	0.955	3.46	(1.24-9.67)	*0.018*	1.52	(0.58-3.94)	0.394
≥ 3	(47)	0.81	(0.24-2.66)	0.722	4.75	(1.30-17.41)	*0.019*	1.54	(0.47-5.03)	0.479
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal [¥]	(106)	0.44	(0.17-1.20)	0.108	0.43	(0.15-1.21)	0.110	0.49	(0.18-1.31)	0.154
Caesarean section only	(63)	0.40	(0.14-1.12)	0.081	0.21	(0.07-0.66)	*0.008*	0.48	(0.17-1.33)	0.159

Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(22)	0.99	(0.38-2.60)	0.983	1.87	(0.63-5.55)	0.257	1.90	(0.72-5.05)	0.197
Low/unspecified forceps	(53)	1.87	(0.95-3.67)	0.069	0.38	(0.65-2.94)	0.407	1.12	(0.58-2.17)	0.740
Rotational forceps	(30)	0.83	(0.32-2.12)	0.690	0.75	(0.21-2.62)	0.652	1.09	(0.44-2.72)	0.854
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(109)	1.45	(0.79-2.66)	0.229	0.91	(0.44-1.86)	0.792	0.91	(0.50-1.63)	0.744
3C/4	(51)	1.25	(0.58-2.67)	0.566	1.39	(0.59-3.24)	0.451	1.32	(0.63-2.76)	0.462
Unspecified	(19)	1.93	(0.61-6.16)	0.265	0.99	(0.26-3.72)	0.986	2.22	(0.69-7.09)	0.179
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.60	(0.31-1.17)	0.133	1.78	(0.83-3.83)	0.140	0.79	(0.42-1.48)	0.458
Unspecified	(92)	1.14	(0.53-2.42)	0.744	1.28	(0.51-3.21)	0.593	0.86	(0.41-1.80)	0.689
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.086	1.00	(1.00-1.00)	0.780	1.00	(1.00-1.00)	0.404

Appendix 3.4 Multivariate analysis of long-term bowel function, maternal intrapartum, OASIS and neonatal characteristics on long-term QoL – respondents post 2002

Characteristic (n/289)		MHQ QoL domains: General Health Perception OR	95% CI	*p*	Incontinence Impact OR	95% CI	*p*	Role Limitations OR	95% CI	*p*
Bowel symptoms at questionnaire completion										
Faecal urgency										
Never	(69)		Reference			Reference			Reference	
Occasionally/Sometimes	(196)	1.63	(0.87-3.07)	0.130	4.29	(2.13-8.63)	*<0.001*	2.04	(1.02-4.11)	*0.045*
Most/All of the time	(24)	6.11	(1.38-27.07)	*0.017*	1.0	---	---	1.0	---	---
Poor flatus control										
Never	(99)		Reference			Reference			Reference	
Occasionally/Sometimes	(148)	0.91	(0.51-1.64)	0.756	2.70	(1.44-5.06)	*0.002*	0.46	(0.23-0.92)	*0.027*
Most/All of the time	(42)	0.99	(0.36-2.69)	0.978	9.95	(2.48-39.94)	*0.001*	0.73	(0.21-2.58)	0.627
Difficulty wiping										
Never	(167)		Reference			Reference			Reference	
Occasionally/Sometimes	(99)	1.56	(0.65-2.08)	0.623	1.03	(0.55-1.94)	0.925	0.80	(0.41-1.55)	0.507
Most/All of the time	(23)	1.69	(0.53-5.42)	0.376	2.80	(0.54-14.45)	0.219	0.82	(0.21-3.20)	0.772
Any faecal leakage										
Absent	(186)		Reference			Reference			Reference	
Present	(103)	1.24	(0.69-2.22)	0.477	1.63	(0.85-3.14)	0.142	2.33	(0.16-4.72)	*0.018*
Maternal characteristics										
Age at OASIS		0.97	(0.91-1.02)	0.247	0.97	(0.91-1.03)	0.333	1.04	(0.98-1.11)	0.187

Years between OASIS and questionnaire completion		1.16	(1.00-1.33)	*0.046*	0.97	(0.83-1.14)	0.699	1.07	(0.91-1.26)	0.428
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(152)	2.69	(0.86-8.40)	0.090	1.30	(0.41-4.10)	0.658	1.14	(0.35-3.70)	0.832
≥ 3	(47)	2.71	(0.69-10.66)	0.154	0.96	(0.23-4.04)	0.956	0.86	(0.20-3.70)	0.843
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal [¥]	(106)	0.38	(0.12-1.21)	0.101	0.79	(0.24-2.56)	0.696	0.80	(0.24-2.64)	0.711
Caesarean section only	(63)	0.18	(0.06-0.62)	*0.006*	0.77	(0.22-2.74)	0.690	0.98	(0.27-3.50)	0.974
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(22)	0.91	(0.33-2.47)	0.852	1.83	(0.55-6.07)	0.323	0.88	(0.28-2.77)	0.822
Low/unspecified forceps	(53)	1.31	(0.65-2.66)	0.449	0.98	(0.45-2.11)	0.955	0.81	(0.37-1.80)	0.607
Rotational forceps	(30)	1.72	(0.64-4.66)	0.283	0.80	(0.27-2.41)	0.688	0.49	(0.17-1.40)	0.182
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(109)	0.95	(0.50-1.78)	0.863	0.72	(0.36-1.44)	0.356	1.46	(0.74-2.90)	0.281
3C/4	(51)	0.78	(0.36-1.69)	0.524	0.50	(0.21-1.19)	0.118	5.00	(1.66-15.02)	*0.004*
Unspecified	(19)	0.80	(0.24-2.71)	0.721	0.61	(0.15-2.44)	0.482	2.00	(0.47-8.56)	0.349
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.96	(0.50-1.87)	0.910	0.54	(0.26-1.12)	0.097	0.90	(0.43-1.89)	0.780
Unspecified	(92)	0.41	(0.19-0.90)	*0.026*	1.08	(0.45-2.59)	0.863	0.93	(0.38-2.25)	0.871
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.791	1.00	(1.00-1.00)	0.345	1.00	(1.00-1.00)	0.674

Characteristic (n)		Physical Limitations			Social Limitations			Personal Relationships		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at questionnaire completion										
Faecal urgency										
Never	(69)		Reference			Reference			Reference	
Occasionally/Sometimes	(196)	3.65	(1.25-10.60)	*0.018*	1.71	(0.57-5.11)	0.335	2.89	(1.00-8.34)	*0.049*
Most/All of the time	(24)	13.71	(3.14-59.90)	*0.001*	14.32	(3.21-63.91)	*<0.001*	9.93	(2.37-41.60)	*0.002*
Poor flatus control										
Never	(99)		Reference			Reference			Reference	
Occasionally/Sometimes	(148)	2.05	(0.91-4.61)	0.084	1.41	(0.56-3.53)	0.468	1.23	(0.53-2.83)	0.630
Most/All of the time	(42)	3.00	(1.02-8.85)	*0.046*	3.29	(1.02-10.58)	*0.046*	0.06	(0.68-6.23)	0.203
Difficulty wiping										
Never	(167)		Reference			Reference			Reference	
Occasionally/Sometimes	(99)	1.75	(0.89-3.44)	0.105	2.01	(0.94-4.30)	0.071	2.36	(1.16-4.83)	*0.018*
Most/All of the time	(23)	0.78	(0.24-2.60)	0.690	0.71	(0.18-2.78)	0.618	1.14	(0.33-3.92)	0.836
Any faecal leakage										
Absent	(186)		Reference			Reference			Reference	
Present	(103)	3.46	(1.78-6.71)	*<0.001*	3.14	(1.50-6.56)	*0.002*	1.83	(0.93-3.60)	0.080
Maternal characteristics										
Age at OASIS		0.99	(0.93-1.06)	0.783	1.03	(0.96-1.12)	0.400	1.01	(0.94-1.08)	0.846
Years between OASIS and questionnaire completion		0.87	(0.73-1.03)	0.114	0.93	(0.77-1.12)	0.446	0.83	(0.69-1.00)	*0.045*
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(152)	1.53	(0.51-4.61)	0.454	2.03	(0.64-6.48)	0.231	1.92	(0.65-5.69)	0.237
≥ 3	(47)	2.13	(0.54-8.50)	0.283	3.22	(0.73-14.31)	0.124	1.68	(0.41-6.98)	0.474
Post-OASIS births										

None	(120)		Reference			Reference			Reference	
Vaginal ¥	(106)	0.56	(0.18-1.79)	0.330	0.44	(0.13-1.48)	0.186	0.89	(0.29-2.74)	0.843
Caesarean section only	(63)	0.99	(0.29-3.45)	0.992	0.83	(0.22-3.08)	0.781	0.40	(0.11-1.48)	0.168
Intrapartum characteristics										
OASIS birth mode										
SVD	(183)		Reference			Reference			Reference	
Kiwi	(22)	1.41	(0.46-4.29)	0.548	0.86	(0.24-3.08)	0.818	0.83	(0.26-2.69)	0.758
Low/unspecified forceps	(53)	1.08	(0.47-2.44)	0.863	0.80	(0.31-2.04)	0.636	0.43	(0.17-1.14)	0.090
Rotational forceps	(30)	0.39	(0.11-1.38)	0.144	0.25	(0.05-1.20)	0.083	0.27	(0.07-1.05)	0.058
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(109)	0.90	(0.42-1.94)	0.786	0.86	(0.36-2.06)	0.734	0.80	(0.35-1.83)	0.593
3C/4	(51)	0.74	(0.28-1.96)	0.548	0.66	(0.22-1.94)	0.444	1.05	(0.40-2.77)	0.928
Unspecified	(19)	1.59	(0.38-6.63)	0.522	0.72	(0.13-3.85)	0.699	3.85	(0.84-17.57)	0.082
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.48	(0.21-1.10)	0.082	0.82	(0.33-2.05)	0.666	0.70	(0.30-1.64)	0.407
Unspecified	(92)	0.93	(0.37-3.37)	0.882	1.00	(0.35-2.87)	0.995	0.91	(0.34-2.46)	0.852
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.966	1.00	(1.00-1.00)	0.340	1.00	(1.00-1.00)	0.834

Characteristic (n)		**Emotions**			**Sleep/Energy**			**Severity Measures**		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at questionnaire completion										
Faecal urgency										
Never	(69)		Reference			Reference			Reference	
Occasionally/Sometimes	(196)	2.78	(1.26-6.14)	*0.012*	2.37	(0.86-6.47)	0.094	2.93	(1.37-6.25)	*0.006*

Most/All of the time	(24)	13.41	(2.45-73.50)	*0.003*	11.77	(2.78-49.91)	*0.001*	5.52	(1.18-25.89)	*0.030*
Poor flatus control										
Never	(99)		Reference			Reference			Reference	
Occasionally/Sometimes	(148)	3.65	(1.82-7.33)	*<0.001*	1.63	(0.70-3.77)	0.256	2.28	(1.17-4.44)	*0.016*
Most/All of the time	(42)	9.52	(3.16-28.68)	*<0.001*	2.54	(0.81-8.01)	0.111	6.63	(1.95-22.35)	*0.002*
Difficulty wiping										
Never	(167)		Reference			Reference			Reference	
Occasionally/Sometimes	(99)	1.06	(0.56-2.00)	0.862	2.20	(1.09-4.45)	0.028	3.03	(1.61-5.70)	*0.001*
Most/All of the time	(23)	2.33	(0.65-8.34)	0.195	0.60	(0.15-2.34)	0.458	7.69	(1.49-39.72)	*0.015*
Any faecal leakage										
Absent	(186)		Reference			Reference			Reference	
Present	(103)	2.06	(1.10-3.85)	*0.024*	2.20	(1.12-4.33)	*0.023*	3.82	(2.00-7.32)	*<0.001*
Maternal characteristics										
Age at OASIS		0.99	(0.93-1.05)	0.639	0.95	(0.89-1.02)	0.151	1.00	(0.94-1.07)	0.959
Years between OASIS and questionnaire completion		1.08	(0.92-1.26)	0.350	0.97	(0.82-1.16)	0.772	1.05	(0.89-1.23)	0.567
Parity (all birth modes)										
1	(90)		Reference			Reference			Reference	
2	(152)	0.85	(0.30-2.44)	0.761	3.07	(1.00-9.48)	0.051	1.56	(0.50-4.85)	0.442
≥ 3	(47)	0.49	(0.13-1.88)	0.297	4.23	(1.03-17.39)	*0.045*	1.22	(0.30-4.98)	0.782
Post-OASIS births										
None	(120)		Reference			Reference			Reference	
Vaginal [¥]	(106)	0.56	(0.18-1.67)	0.296	0.66	(0.21-2.07)	0.477	0.63	(0.20-1.99)	0.431
Caesarean section only	(63)	0.56	(0.17-1.86)	0.340	0.33	(0.09-1.21)	0.095	0.68	(0.19-2.40)	0.547
Intrapartum characteristics										
OASIS birth mode										

SVD	(183)		Reference			Reference			Reference	
Kiwi	(22)	0.88	(0.30-2.63)	0.825	1.51	(0.46-5.01)	0.501	1.56	(0.49-4.91)	0.451
Low/unspecified forceps	(53)	1.60	(0.75-3.39)	0.223	1.17	(0.51-2.68)	0.713	0.81	(0.37-1.79)	0.600
Rotational forceps	(30)	0.90	(0.29-2.73)	0.838	0.60	(0.15-2.44)	0.475	1.13	(0.35-3.65)	0.834
OASIS characteristics										
OASIS classification										
3A	(110)		Reference			Reference			Reference	
3B	(109)	1.17	(0.59-2.33)	0.654	0.63	(0.28-1.42)	0.266	0.64	(0.31-1.31)	0.222
3C/4	(51)	0.95	(0.40-2.26)	0.912	0.88	(0.35-2.25)	0.795	0.85	(0.34-2.12)	0.727
Unspecified	(19)	1.39	(0.35-5.45)	0.639	0.52	(0.11-2.41)	0.400	1.42	(0.35-5.82)	0.628
OASIS repair method										
End-to-end	(105)		Reference			Reference			Reference	
Overlap	(92)	0.50	(0.24-1.05)	0.067	2.13	(0.92-4.94)	0.077	0.73	(0.34-1.55)	0.413
Unspecified	(92)	1.11	(0.46-2.67)	0.811	1.25	(0.46-3.42)	0.669	0.63	(0.27-1.51)	0.304
Neonatal characteristics										
Birthweight		1.00	(1.00-1.00)	0.146	1.00	(1.00-1.00)	0.772	1.00	(1.00-1.00)	0.603

Appendix 4.1 STROBE Statement—Checklist of items that should be included in reports of cohort studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, explain how loss to follow-up was addressed
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage

		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

Appendix 4.2 BASIQ Study antenatal information data capture form

SECTION A: PARTICIPANT INFORMATION

A1 Date of Birth ☐☐ ☐☐ ☐☐☐☐

A2 Ethnic group:

British	☐	Indian	☐
Irish	☐	Pakistani	☐
Other White	☐	Bangladeshi	☐
		Other Asian	☐
White & Black Caribbean	☐		
White & Black African	☐	Black Caribbean	☐
White & Asian	☐	Black African	☐
Other Mixed	☐	Other Black	☐
Chinese	☐	Other Ethnic Group	☐

A3 Parity at enrolment to study: Gravida ☐ Parity ☐ + ☐

SECTION B – PREVIOUS BIRTH HISTORY - FIRST / SECOND / THIRD / FOURTH / FIFTH (circle as applicable)

B 1 / 2 / 3 / 4 / 5 **D D** **M M** **Y Y Y Y**

a Date of baby's birth ☐☐ ☐☐ ☐☐☐☐ Gestation ☐☐ + ☐

b Baby's birth weight ☐☐ lbs ☐☐ oz **OR** ☐☐☐☐ gms Unknown ☐ c Baby's HC: ☐☐☐ cms

d Actual BW plotted on CGC : <10th C ☐ 10th-50th C ☐ 50th-90th C ☐ >90th C ☐

e Last EFW from USS ☐☐☐☐ gms @ Gestation ☐☐ + ☐ Not performed ☐

f Last EFW plotted on CGC : <10th C ☐ 10th-50th C ☐ 50th-90th C ☐ >90th C ☐ n/a ☐

g Type of delivery? SVD ☐ Caesarean before labour ☐ Caesarean during labour ☐ Kiwi ☐

Unspecified forceps ☐ Low forceps ☐ Rotational forceps ☐ Vaginal breech(unassisted) ☐ Vaginal breech (FACH) ☐

h Induction of Labour? Yes ☐ No ☐ Don't know ☐

i Reason for induction: RFM ☐ Static Growth ☐ GDDM ☐ OC ☐ Other ☐ _____ Unknown ☐ n/a ☐

j Documented extent of perineal trauma?

1st degree ☐ 2nd degree ☐ 3a ☐ 3b ☐ 3c ☐ 4th degree ☐ Unspecified OASIS ☐ Episiotomy ☐ Other ☐

k Sutured? Yes ☐ No ☐ Don't know ☐

l Was it a single or multiple birth (eg twins)? Single ☐ Multiple ☐

m Analgaesia in labour: Entonox ☐ Pethidine ☐ Epidural ☐ Water ☐ Aromatherapy ☐

n Waterbirth? Yes ☐ No ☐ Don't know ☐

o Maternal Position at birth: Lithotomy ☐ Supported sitting ☐ All fours ☐ Standing ☐ Left lateral ☐ Not documented ☐

p Place of birth? Home ☐ Hospital - Cons ☐ Hospital - BC ☐

q Length of second stage: ☐ hrs ☐ mins **or** Unknown ☐

Appendix 4.3 BASIQ study MHQ

Birmingham Women's NHS
NHS Foundation Trust

The BASIQ Study

The **effect of** Birth **after** Anal **Sphincter** Injury **on bowel symptoms &** Quality **of Life** Study

Questionnaire

CONFIDENTIAL

If you would like any further information or have queries about the study, please contact:

Sara Webb
[redacted]

Date of completion: _____

EDD/Actual date of delivery: _____

Gestation/PN period on completion: _____

HOW TO FILL IN THIS QUESTIONNAIRE

Questions can be answered by putting a cross in the appropriate box, like this

eg ☒

Your answers will be treated with complete confidentiality and will only be used for research aimed at improving future care for women, like yourself, who have experienced an obstetric anal sphincter injury.

SECTION A: Many women who have had a baby have bowel problems and we would like to know what your bowel problems are and how much they affect you. We would be grateful if you could answer the following questions, thinking about how you have been, on average, **over the past four weeks.**

		Very good	Good	Fair	Poor	Very Poor
A1	How would you describe your health at the present?	☐	☐	☐	☐	☐
		Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
A2	How much do you think your bowel problem affects your life?	☐	☐	☐	☐	☐
		Never	**Occasionally**	**Sometimes**	**Most of the time**	**All of the time**
A3	How often do you have a strong desire to move your bowel which makes you rush to the toilet?	☐	☐	☐	☐	☐
A4	How often do your bowels leak when coughing or sneezing?	☐	☐	☐	☐	☐
A5	How often do your bowels leak when walking?	☐	☐	☐	☐	☐
A6	Do your bowels leak during the rest of the day or night?	☐	☐	☐	☐	☐
A7	Do you have difficulty wiping clean after you have opened your bowels?	☐	☐	☐	☐	☐
A8	Do you have difficulty controlling wind?	☐	☐	☐	☐	☐
A9	Is the leakage from your bowels loose?	☐	☐	☐	☐	☐
A10	Is the leakage from your bowels solid?	☐	☐	☐	☐	☐
		☐	☐	☐	☐	☐

A11 Do your bowels leak during or after sexual intercourse?

If this question is not applicable to you is it because:

A11a the bowel problem makes intercourse impossible ☐ **or** you are not in a sexual relationship ☐

	Not every day	1-2 times	3-4 times	5-6 times	7 or more times
A12 How often do you move your bowels every day?	☐	☐	☐	☐	☐

We would like to know how any bowel problem you have previously described affect your daily working, social and home life.

	Never	Rarely	Sometimes	Often	Always
A13 Does your bowel problem affect you doing the jobs within the home?	☐	☐	☐	☐	☐
A14 Does your bowel problem affect your job, or your normal daily activities outside the home?	☐	☐	☐	☐	☐
A15 Does your bowel problem affect your ability to travel?	☐	☐	☐	☐	☐
A16 Does your bowel problem affect your physical activities (eg, going for a walk, running, sport, gym, etc)?	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

A17	Does your bowel problem limit your social life?					
A18	Does your bowel problem limit your ability to see and visit friends?	☐	☐	☐	☐	☐

We would like to know how any bowel problems you have affect your personal relationships. If any of these questions are not applicable then please leave them blank

		Never	Rarely	Sometimes	Often	Always
A19	Does your bowel problem affect your relationship with your partner?	☐	☐	☐	☐	☐
A20	Does your bowel problem affect your sex life?	☐	☐	☐	☐	☐
A21	Does your bowel problem affect your family life?	☐	☐	☐	☐	☐

We would like to know how any bowel problems you have affect you emotionally.

		Never	Rarely	Sometimes	Often	Always
A22	Does your bowel problem make you feel depressed?	☐	☐	☐	☐	☐
A23	Does your bowel problem make you feel anxious or nervous?	☐	☐	☐	☐	☐
A24	Does your bowel problem make you feel bad about yourself?	☐	☐	☐	☐	☐

We would like to know how any bowel problems you have affect you emotionally.

		Never	Rarely	Sometimes	Often	Always
A25	Does your bowel problem affect your sleep?	☐	☐	☐	☐	
A26	Does your bowel problem make you feel worn out and tired?	☐	☐	☐	☐	

We would like to know how any bowel problems you have affect your lifestyle. Do you do any of the following and if so, how much?

		Never	Rarely	Sometimes	Often	Always
A27	Wear pads to keep clean?	☐	☐	☐	☐	☐
A28	Be careful how much food you eat?	☐	☐	☐	☐	☐
A29	Change your underclothes because they get dirty?	☐	☐	☐	☐	☐
A30	Worry in case you smell?	☐	☐	☐	☐	☐
A31	Get embarrassed because of your bowel problem?	☐	☐	☐	☐	☐

Thank you for your help

Your answers will be treated with complete confidentiality and will only be used for research aimed at improving future care for women, like yourself, who have experienced an obstetric anal sphincter injury

Appendix 4.4 BASIQ study postnatal information data capture form

SECTION A: PARTICIPANT INFORMATION

A1 Planned mode of birth:

Vaginal ☐ Caesarean ☐

Caesarean if requiring augmentation in labour ☐ Caesarean if not spontaneous onset of labour ☐

A2 Reason for choice – tick all as appropriate:

Asymptomatic bowels ☐

No sphincter defects on EAUS ☐

Maternal request – doesn't want elective caesarean section ☐

Maternal request – doesn't want to risk repeat tear ☐

Maternal request – traumatised ☐

Clinical indication non-OASIS ☐

Sphincter defects on EAUS ☐

Symptomatic bowels ☐

A3 Actual mode of birth:

Vaginal ☐ Caesarean ☐

A4 Specific type of birth:

SVD ☐

Ventouse ☐

Low forceps ☐

High Forceps ☐

Unspecified Forceps ☐

Elective caesarean ☐

Emergency caesarean ☐ →

Pre labour ☐

During labour ☐

SECTION B – SUBSEQUENT BIRTH HISTORY - SINGLETON / TWIN 1 / TWIN 2 (circle as applicable)

B 1 / T1 / T2 **D D** **M M** **Y Y Y Y**

a Date of baby's birth ☐☐ ☐☐ ☐☐☐☐ Gestation ☐☐ + ☐

b Baby's birth weight ☐☐ lbs ☐☐ oz **OR** ☐☐☐☐ gms Unknown ☐ c Baby's HC: ☐ cms

d Actual BW plotted on CGC : <10th C ☐ 10th-50th C ☐ 50th-90th C ☐ >90th C ☐

e Last EFW from USS ☐☐☐☐ gms @ Gestation ☐☐ + ☐ Not performed ☐

f Last EFW plotted on CGC : <10th C ☐ 10th-50th C ☐ 50th-90th C ☐ >90th C ☐ n/a ☐

g Type of delivery? SVD ☐ Caesarean before labour ☐ Caesarean during labour ☐ Ventouse ☐

Unspecified forceps ☐ Low forceps ☐ Rotational forceps ☐ Vaginal breech(unassisted) ☐ Vaginal breech (FACH) ☐

h Induction of Labour? Yes ☐ No ☐ Don't know ☐

i Reason for induction: RFM ☐ Static Growth ☐ GDDM ☐ OC ☐ Other ☐ _____ Unknown ☐ n/a ☐

j Documented extent of perineal trauma?

1st degree ☐ 2nd degree ☐ 3a ☐ 3b ☐ 3c ☐ 4th degree ☐ Unspecified OASIS ☐ Episiotomy ☐ Other ☐

k Sutured? Yes ☐ No ☐ Don't know ☐

l Was it a single or multiple birth (eg twins)? Single ☐ Multiple ☐

m Analgaesia in labour: Entonox ☐ Pethidine ☐ Epidural ☐ Water ☐ Aromatherapy ☐

n Waterbirth? Yes ☐ No ☐ Don't know ☐

o Maternal Position at birth: Lithotomy ☐ Supported sitting ☐ All fours ☐ Standing ☐ Left lateral ☐ Not documented ☐

p Place of birth? Home ☐ Hospital - Cons ☐ Hospital - BC ☐

q Length of second stage: ☐ hrs ☐ mins **or** Unknown ☐

Appendix 4.5 Endoanal scan results data form

SECTION A: Antenatal / Postnatal EAUS findings (circle as appropriate)

Date of EAUS ☐☐ ☐☐ ☐☐☐☐

	Coding	Puborectalis	EAS (mid-canal)	IAS	Low canal
Normal	0				
Scarring ≤ 1 hr	0				
Scarring ≥ 2hrs	1				
Defect	1				

Assessor (*Please circle/initial*) SW / _____

Appendix 4.6 BASIQ Study consent form

Affix Patient ID Label here

Birmingham Women's NHS Foundation Trust

Mindlesohn Way
Edgbaston
Birmingham
B15 2TG

Switchboard: [redacted]

Centre: Birmingham Women's NHS Foundation Trust
Study Number:

CONSENT FORM

The effect of **B**irth after **A**nal **S**phincter **I**njury on bowel symptoms and **Q**uality of life: **The BASIQ Study.**

A study into the impact of a subsequent birth on bowel symptoms and its effect on quality of life for women whose previous birth involved an obstetric anal sphincter injury.

Research Team:
Sara Webb [redacted]
Khaled Ismail [redacted]
Matthew Parsons [redacted]

Please initial box

1. I confirm that I have read and understand the information sheet dated 23/09/2013 (version 2) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from Birmingham Women's NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to my GP being informed of my participation in the study. ☐
5. I agree to being contacted in the future for further research into this area. ☐
6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Woman	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

1 copy for woman; 1 copy for researcher; 1 copy to be kept with hospital notes

Appendix 4.7 Multivariate analysis of antenatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on bowel function post the study birth for women who sustained OASIS after January 2002

Characteristic (n/122)		Postnatal bowel symptoms: Faecal Urgency OR	95% CI	*p*	Difficulty wiping clean OR	95% CI	*p*	Poor control of flatus OR	95% CI	*p*	Any faecal leakage OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion													
Faecal urgency													
Absent	(28)		Reference			Reference			Reference			Reference	
Present	(94)	6.31	(1.50-26.62)	*0.012*	0.59	(0.13-2.72)	0.499	0.71	(0.22-2.25)	0.556	3.91	(0.57-26.82)	0.165
Difficulty wiping clean													
Absent	(72)		Reference			Reference			Reference			Reference	
Present	(50)	1.20	(0.30-4.72)	0.798	20.47	(5.75-72.85)	*<0.001*	2.16	(0.80-5.80)	0.129	6.31	(1.82-21.90)	*0.004*
Poor control of flatus													
Absent	(53)		Reference			Reference			Reference			Reference	
Present	(69)	2.26	(0.57-8.95)	0.245	1.02	(0.29-3.64)	0.973	5.26	(1.84-15.07)	*0.002*	0.32	(0.08-1.31)	0.114
Any faecal leakage													
Absent	(91)		Reference			Reference			Reference			Reference	
Present	(31)	18.31	(1.58-212.52)	*0.020*	6.17	(1.44-26.36)	*0.014*	3.13	(0.85-11.49)	0.085	13.96	(3.24-60.15)	*<0.001*
Maternal characteristics													
Age at OASIS		0.97	(0.85-1.11)	0.687	1.29	(1.10-1.52)	*0.002*	1.03	(0.92-1.15)	0.564	1.04	(0.90-1.20)	0.604
Vaginal interval birth(s)													

None	(103)		Reference			Reference			Reference			Reference	
≥ 1	(19)	1.00	(0.11-8.60)	0.998	2.43	(0.30-20.60)	0.415	0.73	(0.12-4.51)	0.735	1.74	(0.21-14.18)	0.605
Parity (all birth modes)													
2	(87)		Reference			Reference			Reference			Reference	
≥ 3	(35)	0.14	(0.03-0.74)	*0.021*	0.42	(0.08-2.13)	0.296	0.42	(0.10-1.72)	0.228	0.79	(0.15-4.27)	0.781
Mode of study birth													
Vaginal	(71)		Reference			Reference			Reference			Reference	
Caesarean section	(51)	0.32	(0.08-1.30)	0.111	1.18	(0.38-3.37)	0.780	0.86	(0.31-2.43)	0.778	0.63	(0.18-2.20)	0.470
Intrapartum characteristics													
OASIS birth mode													
SVD	(73)		Reference			Reference			Reference			Reference	
Kiwi	(16)	4.17	(0.50-34.50)	0.186	0.25	(0.04-1.41)	0.116	3.75	(0.92-15.24)	0.065	3.24	(0.59-17.90)	0.178
Any forceps	(33)	15.62	(2.24-108.73)	*0.005*	0.49	(0.12-1.93)	0.307	1.90	(0.59-6.11)	0.283	1.03	(0.23-4.56)	0.974
OASIS characteristics													
OASIS classification													
3A	(37)		Reference			Reference			Reference			Reference	
3B	(43)	0.21	(0.03-1.64)	0.136	0.57	(0.11-2.86)	0.494	1.87	(0.48-7.36)	0.371	0.61	(0.24-10.71)	0.622
3C/4	(19)	0.02	(0.00-0.23)	*0.002*	0.36	(0.05-2.42)	0.294	1.55	(0.30-7.88)	0.599	5.42	(0.70-42.09)	0.106
Unspecified	(23)	1.35e-07	(0)	0.990	8.24e-08	(0)	0.990	9.03e-07	(0)	0.990	4.43e+07	(0)	0.989
OASIS repair method													
End-to-end	(55)		Reference			Reference			Reference			Reference	
Overlap	(41)	5.52	(0.86-35.44)	0.072	0.46	(0.11-1.97)	0.293	0.67	(0.20-2.22)	0.515	0.86	(0.20-3.73)	0.836
Unspecified	(26)	3362257	(0)	0.990	3697996	(0)	0.991	5076556	(0)	0.989	1.81e-07	(0)	0.990
Neonatal characteristics													
Birthweight (for study birth)		1.00	(1.00-1.00)	*0.023*	1.00	(1.00-1.00)	0.454	1.00	(1.00-1.00)	0.860	1.00	(1.00-1.00)	0.555

Table 4.8 Multivariate analysis of antenatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on QoL post the study birth for women who sustained OASIS after January 2002

Characteristic (n/122)		Postnatal MHQ QoL domains: General Health Perception OR	95% CI	*p*	Incontinence Impact OR	95% CI	*p*	Role Limitations OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion										
Faecal urgency										
Absent	(28)		Reference			Reference			Reference	
Present	(94)	0.64	(0.19-2.24)	0.487	0.69	(0.20-2.38)	0.556	10.35	(1.77-60.50)	*0.010*
Difficulty wiping clean										
Absent	(72)		Reference			Reference			Reference	
Present	(50)	0.76	(0.29-2.00)	0.577	2.16	(0.77-6.03)	0.143	0.46	(0.08-2.53)	0.369
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(69)	0.66	(0.22-1.97)	0.454	0.84	(0.28-2.52)	0.754	1.42	(0.23-8.88)	0.705
Any faecal leakage										
Absent	(91)		Reference			Reference			Reference	
Present	(31)	1.21	(0.40-3.65)	0.740	1.61	(0.47-5.50)	0.449	1.57	(0.20-12.29)	0.670

Corresponding antenatal MHQ domain score									
No impact on QoL (score=0)			Reference			Reference			Reference	
Negative impact on QoL (score ≥ 1)		15.58	(4.71-51.55)	*<0.001*	13.12	(3.88-44.42)	*<0.001*	116.17	(16.57-814.78)	*<0.001*
Maternal characteristics										
Age at OASIS		1.00	(0.90-1.12)	0.943	1.03	(0.92-1.15)	0.646	1.07	(0.91-1.26)	0.403
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
≥ 1	(19)	5.02	(0.77-32.70)	0.091	0.50	(0.08-3.27)	0.466	153.95	(1.70-13909.86)	*0.028*
Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(35)	0.43	(0.10-1.89)	0.265	1.49	(0.34-6.49)	0.594	0.19	(0.02-1.60)	0.127
Mode of study birth										
Vaginal	(71)		Reference			Reference			Reference	
Caesarean section	(51)	1.16	(0.43-3.09)	0.770	1.03	(0.34-3.08)	0.965	0.42	(0.09-1.90)	0.258
Intrapartum characteristics										
OASIS birth mode										
SVD	(73)		Reference			Reference			Reference	
Kiwi	(16)	0.85	(0.21-3.41)	0.813	1.36	(0.34-5.42)	0.668	3.78	(0.36-39.69)	0.268
Any forceps	(33)	0.76	(0.25-3.32)	0.624	0.60	(0.18-2.02)	0.407	1.64	(0.29-9.39)	0.581
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	1.10	(0.31-3.96)	0.883	0.38	(0.09-1.60)	0.188	1.31	(0.12-14.75)	0.829
3C/4	(19)	1.17	(0.27-5.11)	0.837	0.17	(0.03-0.82)	*0.028*	0.29	(0.02-4.05)	0.355
Unspecified	(23)	0.06	(0.00-1.61)	0.095	0.51	(0.02-14.38)	0.693	186.50	(2.57-13537.36)	*0.017*
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	

Overlap	(41)	1.85	(0.55-6.20)	0.320	3.23	(0.92-12.08)	0.068	0.97	(0.13-7.20)	0.979
Unspecified	(26)	10.33	(0.48-223.02)	0.136	0.94	(0.04-21.68)	0.968	0.00	(0.00-0.17)	*0.005*
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.457	1.00	(1.00-1.00)	0.797	1.00	(1.00-1.00)	0.213

Characteristic (n/122)		**Physical Limitations**			**Social Limitations**			**Personal Relationships**		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion										
<u>Faecal urgency</u>										
Absent	(28)	----	----	----	----	-----	----		Reference	
Present	(94)	----	----	----	----	-----	----	4.28	(0.16-112.27)	0.384
<u>Difficulty wiping clean</u>										
Absent	(72)		Reference			Reference			Reference	
Present	(50)	3.17	(0.61-16.39)	0.170	12.73	(0.80-202.15)	0.071	0.27	(0.02-3.38)	0.307
<u>Poor control of flatus</u>										
Absent	(53)		Reference			Reference			Reference	
Present	(69)	1.28	(0.20-8.09)	0.793	0.45	(0.02-9.23)	0.601	0.21	(0.22-1.95)	0.169
<u>Any faecal leakage</u>										
Absent	(91)		Reference			Reference			Reference	
Present	(31)	5.82	(0.92-37.06)	0.062	133.69	(4.25-4202.43)	*0.005*	30.93	(1.92-498.15)	*0.016*
Corresponding antenatal MHQ domain score										
No impact on QoL (score=0)			Reference			Reference			Reference	
A negative impact on QoL (score ≥ 1)		12.19	(1.82-81.89)	*0.010*	124.06	(2.08-7418.75)	*0.021*	17.91	(0.74-433.25)	0.076
Maternal characteristics										
Age at OASIS		1.20	(0.97-1.48)	0.100	1.68	(1.03-2.72)	*0.037*	1.58	(1.10-2.26)	*0.014*

Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
Vaginal	(19)	5.75	(0.38-86.71)	0.207	13.90	(0.15-1329.97)	0.258	1.07	(0.17-67.25)	0.974
Total Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(35)	1.24	(0.15-10.35)	0.844	0.91	(0.04-20.87)	0.953	2.04	(0.08-55.75)	0.672
Mode of study birth										
Vaginal	(71)		Reference			Reference			Reference	
Caesarean section	(51)	4.03	(0.78-20.71)	0.095	4.25	(0.27-67.23)	0.304	0.30	(0.03-2.80)	0.291
Intrapartum characteristics										
OASIS birth mode										
SVD	(73)		Reference			Reference			Reference	
Kiwi/ventouse	(16)	4.54	(0.58-35.69)	0.150	0.08	(0.00-10.26)	0.306	0.11	(0.00-6.64)	0.291
Any forceps	(33)	1.44	(0.20-10.29)	0.718	0.17	(0.01-3.78)	0.259	0.35	(0.03-4.08)	0.403
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	4.47	(0.38-52.38)	0.233	0.05	(0.00-3.13)	0.157	2.15	(0.16-29.66)	0.568
3C/4	(19)	0.77	(0.05-11.36)	0.849	0.09	(0.00-4.16)	0.218	2.13	(0.10-45.44)	0.629
Unspecified	(23)	3.85	(0.15-98.11)	0.414	1.31e+08	(0)	0.991	0.04	(0.00-3.19)	0.148
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	2.67	(0.27-36.10)	0.399	31.45	(0.68-1461.03)	0.078	0.24	(0.02-2.71)	0.248
Unspecified	(26)	2.71	(0.12-60.13)	0.529	2.03e-08	(0)	0.992	9.32	(0.28-315.03)	0.214
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.171	1.00	(1.00-1.00)	0.615	1.00	(1.00-1.00)	0.917

Characteristic (n/122)		**Emotions**			**Sleep/Energy**			**Severity Measures**		

		OR	95% CI	*P*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion										
Faecal urgency										
Absent	(28)		Reference			Reference			Reference	
Present	(94)	0.87	(0.18-4.15)	0.866	0.42	(0.03-5.94)	0.519	0.36	(0.723-1.80)	0.215
Difficulty wiping clean										
Absent	(72)		Reference			Reference			Reference	
Present	(50)	2.07	(0.61-7.00)	0.244	1.20	(0.18-7.79)	0.852	1.71	(0.49-5.97)	0.403
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(69)	0.45	(0.11-1.92)	0.280	1.98	(0.16-24.99)	0.598	1.16	(0.31-4.13)	0.825
Any faecal leakage										
Absent	(91)		Reference			Reference			Reference	
Present	(31)	1.27	(0.30-5.47)	0.748	3.13	(0.48-20.26)	0.232	4.05	(0.93-17.66)	0.062
Corresponding antenatal MHQ domain score										
No impact on QoL (score=0)			Reference			Reference			Reference	
A negative impact on QoL (score ≥ 1)		50.90	(11.01-235.19)	*<0.001*	32.60	(3.63-293.10)	*0.002*	21.27	(4.98-90.81)	*<0.001*
Maternal characteristics										
Age at OASIS		1.09	(0.95-1.26)	0.232	0.95	(0.73-1.24)	0.698	1.08	(0.94-1.25)	0.281
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
Vaginal	(19)	1.62	(0.19-13.81)	0.661	1.07	(0.54-20.99)	0.966	0.28	(0.03-2.87)	0.286
Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(35)	3.24	(0.60-17.44)	0.172	7.89	(0.74-83.72)	0.087	1.61	(0.29-9.00)	0.586

Mode of study birth										
Vaginal	(71)		Reference			Reference			Reference	
Caesarean section	(51)	0.88	(0.25-3.09)	0.835	3.10	(0.36-26.95)	0.305	1.13	(0.33-3.92)	0.848
Intrapartum characteristics										
OASIS birth mode										
SVD	(73)		Reference			Reference			Reference	
Kiwi	(16)	2.38	(0.43-13.16)	0.321	0.49	(0.03-7.31)	0.605	2.17	(0.42-11.24)	0.354
Any forceps	(33)	1.11	(0.24-5.04)	0.897	1.64	(0.17-15.59)	0.669	0.25	(0.05-1.24)	0.090
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	1.06	(0.19-5.78)	0.947	0.45	(0.03-6.92)	0.569	2.64	(0.44-15.74)	0.285
3C/4	(19)	1.16	(0.19-7.16)	0.872	0.20	(0.01-4.10)	0.296	2.47	(0.39-15.78)	0.339
Unspecified	(23)	11.47	(0.36-370.02)	0.169	1371097	(0)	0.995	0.07	(0.00-3.10)	0.170
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	1.42	(0.32-6.39)	0.646	1.16	(0.11-12.11)	0.899	0.71	(0.16-3.10)	0.643
Unspecified	(26)	0.06	(0.00-1.52)	0.087	1.27e-06	(0)	0.995	10.37	(0.29-9.00)	0.586
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.915	1.00	(1.00-1.00)	0.963	1.00	(1.00-1.00)	0.622

Table 4.9 Multivariate analysis of postnatal bowel function, maternal, intrapartum, OASIS and neonatal characteristics on QoL post the study birth for women who sustained OASIS after January 2002

Characteristic (n/122)		Postnatal MHQ QoL domains: General Health Perception			Incontinence Impact			Role Limitations		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at postnatal MHQ completion										
Faecal urgency										
Absent	(28)		Reference			Reference			Reference	
Present	(94)	2.62	(0.84-8.14)	0.096	1.10	(0.29-4.23)	0.885	5.31	(1.36-20.83)	*0.017*
Difficulty wiping clean										
Absent	(72)		Reference			Reference			Reference	
Present	(50)	0.30	(0.11-0.82)	*0.018*	6.28	(2.06-19.14)	*0.001*	0.43	(0.12-1.50)	0.186
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(69)	0.69	(0.25-1.86)	0.456	4.00	(1.26-12.70)	*0.019*	1.16	(0.35-3.91)	0.807
Any faecal leakage										
Absent	(91)		Reference			Reference			Reference	
Present	(31)	2.49	(0.85-7.25)	0.095	2.54	(0.76-8.46)	0.129	3.19	(0.58-17.65)	0.185
Maternal characteristics										
Age at OASIS		1.02	(0.93-1.13)	0.624	0.94	(0.84-1.05)	0.283	1.13	(0.99-1.29)	0.082
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	

≥ 1	(19)	2.30	(0.46-11.57)	0.311	0.20	(0.03-1.46)	0.112	11.17	(0.70-178.44)	0.088
Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(35)	0.96	(0.27-3.41)	0.945	6.53	(1.29-33.05)	*0.023*	0.85	(0.20-3.66)	0.825
Mode of study birth										
Vaginal	(71)		Reference			Reference			Reference	
Caesarean section	(51)	1.57	(0.66-3.72)	0.304	3.14	(1.11-8.88)	*0.031*	0.85	(0.29-2.51)	0.764
Intrapartum characteristics										
OASIS birth mode										
SVD	(73)		Reference			Reference			Reference	
Kiwi	(16)	0.42	(0.11-1.56)	0.194	1.61	(0.38-6.78)	0.519	0.80	(0.16-3.93)	0.780
Any forceps	(33)	0.39	(0.14-1.12)	0.080	0.51	(0.15-1.72)	0.276	0.43	(0.11-1.62)	0.212
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	0.97	(0.30-3.18)	0.965	0.32	(0.08-1.30)	0.112	3.03	(0.64-14.40)	0.164
3C/4	(19)	1.10	(0.26-4.61)	0.900	0.19	(0.03-1.16)	0.071	2.31	(0.36-14.80)	0.376
Unspecified	(23)	0.08	(0.00-1.35)	0.079	0.19	(0.01-5.99)	0.342	14.64	(0.45-472.78)	0.130
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	0.68	(0.24-1.93)	0.473	3.92	(1.04-14.75)	*0.043*	0.85	(0.21-3.40)	0.816
Unspecified	(26)	4.92	(0.34-71.73)	0.244	1.11	(0.04-27.84)	0.950	0.09	(0.00-2.25)	0.143
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.784	1.00	(1.00-1.00)	0.336	1.00	(1.00-1.00)	0.551

Characteristic (n/122)	**Physical Limitations**	**Social Limitations**	**Personal Relationships**

		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion										
Faecal urgency										
Absent	(28)	----	----	----	----	----	----	----	----	----
Present	(94)	----	----	----	----	----	----	----	----	----
Difficulty wiping clean										
Absent	(72)		Reference			Reference			Reference	
Present	(50)	6.33	(1.45-27.66)	*0.014*	3.70	(0.56-24.34)	0.173	3.88	(0.56-26.96)	0.171
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(69)	5.63	(0.76-41.51)	0.090	2.03	(0.25-16.87)	0.512	6.00	(0.63-57.14)	0.119
Any faecal leakage										
Absent	(91)		Reference			Reference			Reference	
Present	(31)	2.47	(0.60-10.16)	0.211	13.23	(1.89-92.62)	*0.009*	3.19	(0.53-19.09)	0.205
Maternal characteristics										
Age at OASIS		1.02	(0.87-1.21)	0.793	1.06	(0.86-1.33)	0.580	1.22	(0.98-1.52)	0.077
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
Vaginal	(19)	3.64	(0.23-57.94)	0.360	5.33	(0.20-141.93)	0.317	0.73	(0.04-14.50)	0.838
Total Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(35)	3.21	(0.48-21.29)	0.227	3.08	(0.30-31.72)	0.345	11.63	(0.99-136.81)	0.051
Mode of study birth										
Vaginal	(71)		Reference			Reference			Reference	
Caesarean section	(51)	4.51	(0.99-20.58)	0.052	8.60	(1.00-74.07)	0.050	0.89	(0.14-5.57)	0.904
Intrapartum characteristics										
OASIS birth mode										
SVD	(73)		Reference			Reference			Reference	

Kiwi/ventouse	(16)	4.06	(0.56-29.37)	0.165	0.29	(0.01-6.56)	0.435	0.72	(0.05-10.99)	0.812
Any forceps	(33)	0.69	(0.14-3.51)	0.659	0.23	(0.02-2.51)	0.229	0.17	(0.02-1.40)	0.100
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	8.87	(0.99-79.34)	0.051	0.40	(0.03-4.61)	0.460	4.10	(0.36-46.07)	0.259
3C/4	(19)	1.00	(0.10-10.18)	0.997	0.05	(0.00-1.59)	0.090	0.28	(0.01-5.31)	0.392
Unspecified	(23)	1.02	(0.04-27.94)	0.989	535480.7	(0)	0.995	0.02	(0.00-1.10)	0.056
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	0.87	(0.16-4.69)	0.868	4.10	(0.40-41.03)	0.236	0.17	(0.02-1.87)	0.147
Unspecified	(26)	2.84	(0.14-57.57)	0.498	5.62e-07	(0)	0.995	3.94	(0.14-108.95)	0.418
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.395	1.00	(1.00-1.00)	0.750	1.00	(1.00-1.00)	0.319

Characteristic (n/122)		**Emotions**			**Sleep/Energy**			**Severity Measures**		
		OR	95% CI	*p*	OR	95% CI	*p*	OR	95% CI	*p*
Bowel symptoms at antenatal MHQ completion										
Faecal urgency										
Absent	(28)		Reference			Reference			Reference	
Present	(94)	3.10	(0.74-13.02)	0.123	12.58	(0.85-186.25)	0.066	2.11	(0.37-11.91)	0.397
Difficulty wiping clean										
Absent	(72)		Reference			Reference			Reference	
Present	(50)	4.32	(1.54-12.17)	*0.005*	1.16	(0.22-5.92)	0.862	6.47	(1.96-21.36)	*0.002*
Poor control of flatus										
Absent	(53)		Reference			Reference			Reference	
Present	(69)	2.02	(0.63-6.52)	0.240	0.53	(0.08-3.44)	0.506	1.56	(0.42-5.75)	0.506

Any faecal leakage										
Absent	(91)		Reference			Reference			Reference	
Present	(31)	1.59	(0.50-5.10)	0.437	5.39	(0.99-29.30)	0.051	7.22	(1.95-26.77)	*0.003*
Maternal characteristics										
Age at OASIS		1.02	(0.91-1.15)	0.732	0.99	(0.82-1.20)	0.947	0.96	(0.84-1.10)	0.536
Vaginal interval birth(s)										
None	(103)		Reference			Reference			Reference	
Vaginal	(19)	0.57	(0.09-3.67)	0.555	1.00	(0.08-12.64)	0.996	0.26	(0.03-2.65)	0.253
Parity (all birth modes)										
2	(87)		Reference			Reference			Reference	
≥ 3	(35)	8.50	(1.86-38.92)	*0.006*	5.71	(0.93-35.23)	0.061	3.96	(0.78-20.09)	0.096
Mode of study birth										
Vaginal	(71)		Reference			Reference			Reference	
Caesarean section	(51)	2.15	(0.77-6.01)	0.143	4.66	(0.90-24.21)	0.068	2.39	(0.75-7.62)	0.141
Intrapartum characteristics										
OASIS birth mode										
SVD	(73)		Reference			Reference			Reference	
Kiwi	(16)	1.24	(0.30-5.06)	0.765	0.36	(0.03-4.73)	0.433	1.38	(0.28-6.90)	0.698
Any forceps	(33)	0.43	(0.12-1.50)	0.184	0.54	(0.08-3.47)	0.514	0.23	(0.05-1.00)	0.050
OASIS characteristics										
OASIS classification										
3A	(37)		Reference			Reference			Reference	
3B	(43)	1.21	(0.30-4.92)	0.789	1.33	(0.14-12.58)	0.803	3.88	(0.78-19.38)	0.099
3C/4	(19)	1.66	(0.32-8.70)	0.547	0.74	(0.04-14.93)	0.842	4.06	(0.57-28.87)	0.161
Unspecified	(23)	2.16	(0.11-42.13)	0.612	1210524	(0)	0.991	0.07	(0.00-1.92)	0.115
OASIS repair method										
End-to-end	(55)		Reference			Reference			Reference	
Overlap	(41)	0.94	(0.27-3.31)	0.924	0.48	(0.07-3.41)	0.460	0.37	(0.09-1.53)	0.171

Unspecified	(26)	0.28	(0.02-4.33)	0.361	2.70e-06	(0)	0.992	4.29	(0.22-83.44)	0.336
Neonatal characteristics										
Birthweight (for study birth)		1.00	(1.00-1.00)	0.734	1.00	(1.00-1.00)	0.975	1.00	(1.00-1.00)	0.820

References

1. Kettle C, Dowswell T, Ismail K. Continuous and interrupted suturing techniques for repair of episiotomy or second degree tears. Cochrane Database of Systematic Reviews. 2012(11).

2. Marsh F, Lynne R, Christine L, Alison W. Obstetric anal sphincter injury in the UK and its effect on bowel, bladder and sexual function. European Journal of Obstetrics Gynecology and Reproductive Biology. 2011;154(2):223-7.

3. Keighley MRB, Perston Y, Bradshaw E, Hayes J, Keighley DM, Webb S. The social, psychological, emotional morbidity and adjustment techniques for women with anal incontinence following Obstetric Anal Sphincter Injury: use of a word picture to identify a hidden syndrome. . BMC Pregnancy & Childbirth. 2016;16.

4. Boreham M, Richter H, Kenton K, Nager C, Gregory W, Aronson M. Anal incontinence in women presenting for gynecologic care: prevalence, risk factors and impact upon quality of life. American Journal of Obstetrics & Gynecology. 2005;192:1637-42.

5. Leigh R, Turnberg L. Faecal incontinence: the unvoiced symptom. Lancet. 1982;1(8285):1349-51.

6. Lo J, Osterweil P, Li H, Mori T, Eden K, Guise J. Quality of life in women with postpartum anal incontinence. Obstet Gynecol. 2010;115(4):809-14.

7. Mous M, Mullar S, de Leeuw JW. Long-term effects of anal sphincter rupture during vaginal delivery: faecal incontinence and sexual complaints. BJOG : an international journal of obstetrics and gynaecology. 2008;115:234-8.

8. Sultan AH, Kamm MA, Hudson CN, Bartram CI. Third degree obstetric anal sphincter tears: risk factors and outcome of primary repair. BMJ. 1994;308(6933):887-91.

9. Nichols CM, Nam M, Ramakrishnan V, Lamb EH, Currie N. Anal sphincter defects and bowel symptoms in women with and without recognized anal sphincter trauma. American Journal of Obstetrics & Gynecology. 2006;194(5):1450-5.

10. Baghestan E IL, Bordahl PE, Rasmussen S. Trends in risk factors for obstetric anal sphincter injuries in Norway. Obstet Gynecol. 2010;116:25-35.

11. Laine K, Gissler M, Pirhonen J. Changing incidence of anal sphincter tears in four Nordic countries through the last decades. European Journal of Obstetrics Gynecology and Reproductive Biology. 2009;146:71-5.

12. Sultan AH, Kamm M, Hudson C, Thomas J, Bartram C. Anal-sphincter disruption during vaginal delivery. New England Journal of Medicine. 1993;329(26):1905-11.

13. Fretheim A, Odgaard-Jensen J, Rottingen J, Reiner L, Vangan S, Tanbo T. The impact of an intervention programme employing a hands-on technique to reduce the incidence of anal sphincter tears: interrupted time-series reanalysis. BMJ Open. 2013(3:e003355).

14. Gurol-Urganci I CD, Edozien LC, Mahmood TA, Adams EJ, Richmond DH, Templeton A, van der Meulen JH. Third- and fourth-degree perineal tears among primiparous women in England between 2000 and 2012: time trends and risk factors. BJOG. 2013;120:1516-25.

15. RCOG. Third- and Fourth-degree Perineal Tears, Management (Green-top 29). RCOG Greentop Guidelines. 2001.

16. Thiagamoorthy G, Johnson A, Thakar R, Sultan AH. National survey of perineal trauma and its subsequent management in the United Kingdom. International Urogynecology Journal and Pelvic Floor Dysfunction. 2014;25(12):1621-7.

17. Handa VL DB, Gilbert WM. Obstetric anal sphincter lacerations. Obstt Gynecol. 2001;98:225-30.

18. Raisanen S, Vehvilainen-Julkunen K, Cartwright R, Gissler M, Heinonen S. A prior cesarean section and incidence of obstetric anal sphincter injury. International Urogynecology Journal. 2013;24(8):1331-9.

19. De Leeuw JW, Vierhout ME, Struijk PC, Hop WCJ, Wallenburg HCS. Anal sphincter damage after vaginal delivery: Functional outcome and risk factors for fecal incontinence. Acta Obstetricia et Gynecologica Scandinavica. 2001;80(9):830-4.

20. Ampt A, Ford J, Roberts CL. Trends in predictors of major perineal trauma at childbirth. Journal of Paediatrics and Child Health. 2012;48.

21. Baghestan E, Irgens L, Rasmussen S. Risk of recurrence and subsequent delivery after obstetric anal sphincter injuries. BJOG: An International Journal of Obstetrics & Gynaecology. 2012;119(1):62-9.

22. Gerdin E, Sverrisdottir G, Badi A, Carlsson B, Graf W. The role of maternal age and episiotomy in the risk of anal sphincter tears during childbirth. Australian & New Zealand Journal of Obstetrics & Gynaecology. 2007;47(4):286-90.

23. Landy H, Laughon S, Bailit JL, Kominiarek M, Gonzalez-Quintero V, Ramirez M, et al. Characteristics associated with severe perineal and cervical lacerations during vaginal delivery. Obstet Gynecol. 2011;117(3):627-35.

24. Raisanen S V-JK, Gissler M, Heinonen S. The increased incidence of obstetric anal sphincter rupture - An emerging trend in Finland. Prev Med. 2009;49:535-40.

25. Legino LJ, Woods MP, Rayburn WF, McGoogan LS. Third- and fourth-degree perineal tears. 50 year's experience at a university hospital. Journal of Reproductive Medicine. 1988;33(5):423-6.

26. Angioli R G-MO, Cantuaria G, O'Sullivan MJ. Severe perineal lacerations during vaginal delivery: the University of Miami experience. Am J Obstet Gynecol. 2000;182:1083-5.

27. O'Mahony F, Hofmeyr GJ, Menon V. Choice of instruments for assisted vaginal delivery. Cochrane Database of Systematic Reviews. 2010(11).

28. De Leeuw JW, Struijk PC, Vierhout ME, Wallenburg HCS. Risk factors for third degree perineal ruptures during delivery. British Journal of Obstetrics and Gynaecology. 2001;108(4):383-7.

29. Jangö H, J. Langhoff-Roos, S. Rosthøj, A. Sakse. Risk factors of recurrent anal sphincter ruptures: a population-based cohort study. BJOG. 2012;119(13):1640-7.

30. Kalis V LK, de Leeuw J, Ismail K, Tincello D. Classification of episiotomy; towards a standardisation of terminology. BJOG. 2012;119(5):522-6.

31. de Leeuw J, de Wit C, Bruinse H, Kuijken J. Mediolateral episiotomy reduces the risk for anal sphincter injury during operative vaginal delivery. BJOG: An International Journal of Obstetrics & Gynaecology. 2008;115:104-8.

32. Raisanen S, Vehvilainen-Julkunen K, Gissler M, Heinon S. Hospital-based lateral episiotomy and obstetric anal sphincter injury rates: a retrospective population-based register study. Am J Obstet Gynecol. 2012;206(4):347.e.e6.

33. Raisanen S, Vehvilainen-Julkunen K, Gissler M, Heinon S. Lateral episiotomy protects primiparous but not multiparous women from obstetric anal sphincter rupture. Acta Obstetricia et Gynecologica Scandinavica. 2009;88(12):1365-72.

34. Andrews V, Sultan A, Thakar R, Jones P. Risk factors for obstetric anal sphincter injury; a prospective study. Birth. 2006;32(2):177-22.

35. Ekeus C, Nilsson E, Gottvall K. Increasing incidence of anal sphincter tears among primiparas in Sweden: A population-based register study. Acta Obstetricia et Gynecologica Scandinavica. 2008;87(5):564-73.

36. Webb SS, Hemming K, Khalfaoui MY, Henriksen TB, Kindberg S, Stensgaard S, et al. An obstetric sphincter injury risk identification system (OSIRIS): is this a clinically useful tool? International Urogynecology Journal. 2016:1-8.

37. Williams A, Tincello D, White S, Adams E, Alfirevic Z, Richmond D. Risk scoring system for prediction of obstetric anal sphincter injury. BJOG: An International Journal of Obstetrics & Gynaecology. 2005;112:1066-9.

38. Laine K, Skeldestad F, Sandvick L, Staff A. Incidence of obstetric anal sphincter injuries after training to protect the perineum: cohort study. BMJ Open. 2012;2:e001649.

39. Laine K, Pirhonen T, Rolland R, Pirhonen J. Decreasing the Incidence of Anal Sphincter Tears During Delivery. Obstetrics & Gynecology. 2008;111(5):1053-7.

40. RCOG. Third- and Fourth-degree Perineal Tears, Management (Green-top 29). RCOG Greentop Guidleines. 2015(2).

41. Koelbl H, Igawa T, Salvatore S, Laterza RM, Lowry A, Sievert K, et al. Pathophysiology of urinary incontinence, faecal incontinence and pelvic organ prolapse. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence. 5th ed. [place unknown]: ICUD-EAU; 2013. p. 261-359.

42. Fernando RJ, Sultan AHH, Kettle C, Thakar R. Methods of repair for obstetric anal sphincter injury. Cochrane Database of Systematic Reviews. 2013(12).

43. Sultan AH, Monga AK, Kumar D, Stanton SL. Primary repair for obstetric anal sphincter injury using the overlap technique. BJOG : an international journal of obstetrics and gynaecology. 1999;106:318-23.

44. Scheer I, Thakar R, Sultan AH. Mode of delivery after previous obstetric anal sphincter injuries (OASIS)-a reappraisal? International Urogynecology Journal and Pelvic Floor Dysfunction. 2009;20(9):1095-101.

45. Santoro GA, Di Falco G. Atlas of Endoanal and Endorectal Ultrasonography. Staging and Treatment Options for Anorectal Cancer. Italy: Springer-Verlag; 2004.

46. Abdool Z, Sultan AH, Thakar R. Ultrasound imaging of the anal sphincter complex: a review. The British Journal of Radiology. 2011;85:865-75.

47. Bartrum C, Frudinger A. Handbook of anal endosonography. Petersfield, UK: Wrightson Biomedical Publishing Ltd; 1997.

48. Marshall K WD, Baxter D. Faecal incontinence after childbirth. [letter]. BJOG. 1997;104:870.

49. MacArthur C BD, Keighley MR. Faecal incontinence after childbirth. BJOG. 1997;104:46-50.

50. Khullar V DR, Toozs-Hobson P, Cardozo L Prevalence of faecal incontinence among women with urinary incontinence. BJOG. 1998;105:1211-3.

51. Avery K, Bosch J, Gotoh M, Naughton M, Jackson S, Radley S, et al. Questionnaires to Assess Urinary and Anal Incontinence: Review and Recommendations. The Journal of Urology. 2007;177:39-49.

52. Abrams P, Cardozo L, Khoury S, Wein Ae. Incontinence. 4th Consultation on Incontinence. Health Publication, United Kingdom2009.

53. Rockwood T, Church J, Fleshman J, Kane R, Mavrantonia C, Thorson A, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. Dis Colon Rectum. 2000;43(9).

54. Bugg GJ KE, Hosker G A new condition-specific health-related quality of life questionnaire for the assessment of women with anal incontinence. BJOG. 2001;108:1057-67.

55. Hiller L, Bradshaw HD, Radley SC, Radley S. Criterion validity of the BBUSQ-22: a questionnaire assessing bowel and urinary tract symptoms in women. International Urogynecology Journal. 2007;18(10):1133-7.

56. Jorge J, Wexner S. Etiology and management of fecal incontinence. Dis Colon Rectum. 1993;36:77-97.

57. Vaizey CJ, Carapeti E, Cahill J, Kamm M. Prospective comparison of faecal incontinence grading systems. Gut. 1999;44(77).

58. Reilly W, Talley N, Pemberton J, Zinsmeister A. Validation of a questionnaire to assess fecal incontinence and associated risk factors: Fecal Incontinence Questionnaire. Dis Colon Rectum. 2000;43(146).

59. O'Keefe E, Talley N, Tangalos E, Zinsmeister A. A bowel symptom questionnaire for the elderly. J Gerontol. 1992;47(M116).

60. Cockell SJ, Oates-Johnson T, Gilmour DT, Vallis TM, Turnbull GK. Postpartum flatal and fecal incontinence quality-of-life scale: a disease- and population-specific measure. Qualitative Health Research. 2003;13(8):1132-45.

61. Osterberg A, Graf W, Karlbom U, Pahlman L. Evaluation of a questionnaire in the assessment of patients with faecal incontinence and constipation. Scand J Gastroenterol. 1996;31(575).

62. Eypasch E, Williams J, Wood-Dauphinee S, Ure B, Schmulling C, Neugebauer E, et al. Gastrointestinal Quality of Life Index: development, validation and application of a new instrument. British Journal of Surgery. 1995;82(216).

63. Thiagamoorthy G, Johnson A, Thakar R, Sultan A. National audit to assess the true incidence of perineal trauma and its subsequent management in the United Kingdom. BJOG: An International Journal of Obstetrics and Gynaecology. 2013;120:478-9.

64. Faltin D, Petignat P, Reuse C, Drumps P, Nunno C, Pierret B, et al. A prospective cohort study of vaginal delivery after a previous anal sphincter tear. Neurourology and Urodynamics. 2005;24:5-6.

65. Stroup D, Berlin J, Morton S, Olkin I, Williamson G, Rennie D, et al. Meta-analysis of observational studies in epidemiology. JAMA. 2000(283):2008-12.

66. Webb S, Yates D, Ismail K. The impact of subsequent birth on women with previous Ostetric Sphincter Injury (OASIS) on Quality of Life (QoL) and bowel function: a systematic review. PROSPERO 2014:CRD420140092102014. Available from: http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42014009210.

67. Norton C, Christiansen J, Butler U, Harai D, Nelson R, Pemberton J, et al. Anal incontinence. In: Ambrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence: Second international consultation on incontinence. Plymouth: Health Books; 2002.

68. Munn Z, Moola S, Riitano D, Lisy K. The development of a critical appraisal tool for use in systematic reviews addressng questions in prevalence. International Journal of Health Policy and Management. 2014;3(3):123-8.

69. Wells G, Shea B, O'Connell D, Peterson J, Welch V, Losos M, et al. The Newcastle-Ottawa Scvale (NOS) for assessing the quality of nonrandomized studies in meta-analyses. 2009. Available from: http://www.ohri.ca/programs/clinical_epidemiology/oxford.htm.

70. Review Manager (REVMAN) [Computer programm] Version 5.2. Copenhagen. The Nordic Cochrane Centre: The Cochrane Collaboration, 2012.

71. Higgins J, Thompson S, Deeks J, Altman D. Measuring inconsistency in meta-analyses. British Medical Journal. 2003(327):557-60.

72. Sze EH. Anal incontinence among women with one versus two complete third-degree perineal lacerations. International Journal of Gynaecology & Obstetrics. 2005;90(3):213-7.

73. Kumar R. Anal incontinence and quality of life following obstetric anal sphincter injury. Archives of Gynecology and Obstetrics. 2012;285(3):591-7.

74. Sze EH. Prevalence and severity of anal incontinence in women with and without additional vaginal deliveries after a fourth-degree perineal laceration. Diseases of the colon and rectum. 2005;48(1):66-9.

75. Sangalli MR, Floris L, Faltin D, Weil A. Anal incontinence in women with third or fourth degree perineal tears and subsequent vaginal deliveries. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2000;40(3):244-8.

76. Nordenstam J, Altman D, Brismar S, Zetterstrom J. Natural progression of anal incontinence after childbirth. International Urogynecology Journal. 2009;20:1029-35.

77. De JWJ, Vierhout ME, Struijk PC, Hop WC, Wallenburg HC. Anal sphincter damage after vaginal delivery: functional outcome and risk factors for fecal incontinence. Acta Obstetricia et Gynecologica Scandinavica. 2001;80(9):830-4.

78. Huebner M, Gramlich NK, Rothmund R, Nappi L, Abele H, Becker S. Fecal incontinence after obstetric anal sphincter injuries. International Journal of Gynecology and Obstetrics. 2013;121(1):74-7.

79. Soerensen MM, Buntzen S, Bek KM, Laurberg S. Complete obstetric anal sphincter tear and risk of long-term fecal incontinence: a cohort study. Diseases of the Colon & Rectum. 2013;56(8):992-1001.

80. Bek KM, Laurberg S. Risks of anal incontinence from subsequent vaginal delivery after a complete obstetric anal sphincter tear. British Journal of Obstetrics & Gynaecology. 1992;99(9):724-6.

81. Reid A, Beggs A, Sultan A, Roos A, Thacker R. Outcome of repair of obstetric anal sphincter injuries after three years. International Journal of Gynaecology & Obstetrics. 2014;127(1):47-50.

82. Poen AC, Felt-Bersma RJ, Strijers RL, Dekker GA, Cuesta MA, Meuwissen SG. Third-degree obstetric perineal tear: long-term clinical and functional results after primary repair. British Journal of Surgery. 1998;85(10):1433-8.

83. Visscher AP, Lam TJ, Hart N, Felt-Bersma RJF. Fecal incontinence, sexual complaints, and anorectal function after third-degree obstetric anal sphincter injury (OASI): 5-Year follow-up. International Urogynecology Journal and Pelvic Floor Dysfunction. 2014;25(5):607-13.

84. Harkin R, Fitzpatrick M, O'Connell PR, O'Herlihy C. Anal sphincter disruption at vaginal delivery: is recurrence predictable? European Journal of Obstetrics, Gynecology, & Reproductive Biology. 2003;109(2):149-52.

85. Dilmaghani-Tabriz D, Soliman N. Delivery after third-or fourth-degree perineal tear. BJOG: An International Journal of Obstetrics and Gynaecology. 2012;119.

86. Tetzschner T, Sorensen M, Lose G, Christiansen J. Anal and urinary incontinence in women with obstetric anal sphincter rupture. British Journal of Obstetrics & Gynaecology. 1996;103(10):1034-40.

87. Walker HJ, Gelman W, Thomas JM, Bearn PE, McWilliams D. Does vaginal delivery after Obstetric Anal Sphincter Injury (OASI) cause further damage? International Urogynecology Journal and Pelvic Floor Dysfunction. 2009;20(3 SUPPL.):S278-9.

88. Bondili A, Siddiqui I, Nichols W, Kettle C, Cooper J, O'Mahony F, et al. Management of pregnancies following third and fourth degree perineal tears: A multi disciplinary approach. International Urogynecology Journal and Pelvic Floor Dysfunction. 2011;22:S120-1.

89. Younis J, Rajendran N, Walker H, Wolf G, McWilliams D, Bearn P. Deterioration of anal sphincter function following second vaginal delivery in women with previous intrapartum perineal tears. Colorectal Disease. 2010;12.

90. An V, D'Souza B, Thomas E, Schierlitz L, Woods R, Keck J. Obstetric anal sphincter injuries; outcome and function after subsequent deliveries. Triparate Colorectal Meeting of the American Society of Colon and Rectal Surgerons, ASCRS; Association of Coloprotology of GB and Ireland; the Section of Coloproctology, Royal Society of Medicine; the Colon and Rectal Surgery Section, Royal Australasian Birmingham United Kingdom: Conference Publication (var. pagings). 16; 2014. p. 89.

91. Naidu M, Sultan A, Thakar R. Outcome of anal symptoms and anorectal function following two obstetric anal sphincter injuries (OASIS) - a prospective case controlled study. International Urogynaecology Journal and Pelvic Floor Dysfunction 40th Annual Meeting of the International Urogynecological Association, IUGA 2015; Nice, France2015. p. S40-S1.

92. Jordan P, Naidu M, Sultan A, Thacker R. Effect of subsequent vaginal delivery on bowel symptoms and anorectal function in women who sustained a previous obstetric anal sphincter injury (OASI). International Urogynaecology Journal and Pelvic Floor Dysfunction 40th Annual Meeting of the International Urogynecological Association, IUGA 2015; Nice, France: Conference Publication (var. pagings). 26 (1 SUPPL. 1); 2015. p. S40-S1.

93. Karmarkar R, Bhide AA, Digesu A, Khullar V, Fernando R. Mode of deliveryafter previous obstetric anal sphincter injuries (OASIS)-a prospective observational study. International Urogynecology Journal and Pelvic Floor Dysfunction. 2014;1):S190-S1.

94. Fitzpatrick M, Cassidy M, Barussaud M, Hehir M, O'Herlihy C. Does anal sphincter injury preclude subsequent vaginal delivery? European Journal of Obstetrics Gynecology and Reproductive Biology. 2016;198:30-4.

95. Jordan PA, Naidu M, Sultan AH, Thakar R. Effect of subsequent vaginal delivery on bowel symptoms and anorectal function in women who sustained a previous obstetric anal sphincter injury (OASI). International Urogynecology Journal and Pelvic Floor Dysfunction. 2015;1):S45-S6.

96. Daly JO, Sultan AH, Van KW, Thakar R. Outcome of childbirth after previous obstetric anal sphincter injury. International Urogynecology Journal and Pelvic Floor Dysfunction. 2013;24:S69-S70.

97. De Leeuw JW, Vierhout ME, Struijk PC, Hop WC, Wallenburg HC. Anal sphincter damage after vaginal delivery: functional outcome and risk factors for fecal incontinence. Acta Obstetricia et Gynecologica Scandinavica. 2001;80(9):830-4.

98. Faltin DL, Sangalli MR, Roche B, Floris L, Boulvain M, Weil A. Does a second delivery increase the risk of anal incontinence? BJOG: An International Journal of Obstetrics & Gynaecology. 2001;108(7):684-8.

99. Karmarkar R, Bhide A, Digesu A, Khullar V, Fernando R. Mode of delivery after previous obstetric anal sphincter injuries (OASIS). European Journal of Obstetrics Gynecology and Reproductive Biology. 2015;194:7-10.

100. Samarasekera DN, Bekhit MT, Wright Y, Lowndes RH, Stanley KP, Preston JP, et al. Long-term anal continence and quality of life following postpartum anal sphincter injury. Colorectal Disease. 2008;10(8):793-9.

101. Visscher AP, Lam TJ, Hart NA, Mulder CJ, Felt-Bersma RJ. Anal incontinence, sexual complaints, and anorectal function in patients with a third degree anal sphincter rupture: Long term follow-up. Gastroenterology. 2013;144(5 SUPPL. 1).

102. Wagenius J, Laurin J. Clinical symptoms after anal sphincter rupture: a retrospective study. Acta Obstetricia et Gynecologica Scandinavica. 2003;82(3):246-50.

103. Yousif S, Eogan M. Mode of delivery after previus anal sphincter injury (ASI): Role of the perineal clinic. Irish Journal of Medical Science. 2011;180.

104. Reeves B, Deeks J, Higgins J, Wells G. Chapter 13: Including non-randomised studies. In: Higgins J, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5-0-1. www.cochrane-handbook.org: The Cochrane Collaboration 2008.

105. Andrews V, Shelmeridine S, Sultan AH, Thakar R. Anal and urinary incontinence 4 years after a vaginal delivery. International Urogynecology Journal and Pelvic Floor Dysfunction. 2013;24(1):55-60.

106. Williams A, Adams E, Tincello D, Alfirevic Z, Wakinshaw S, Richmond D. How to repair and anal sphincter injury after vaginal delivery: results of a randomised controlled trial. BJOG: An International Journal of Obstetrics & Gynaecology. 2006;113:201-7.

107. StataCorp. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP; 2015.

108. Corp I. SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp; 2014.

109. Fernando R, Sultan AH, Kettle C, Radley S, Jones P, O'Brien P. Repair techniques for Obstetric Anal Sphincter Injuries. A randomized controlled trial. Obstet Gynecol. 2006;107(6):1261-8.

110. Garcia V, Rogers R, Kim S, Hall R, HKammerer-Doak D. Primary repair of obstetric anal sphincter laceration: A randomized trial of two surgical techniques. American Journal of Obstetrics & Gynecology. 2005;192:1697-701.

111. Palm A, Israelsson L, Bolin M, Danielsson I. Symptoms after obstetric sphincter injuries have little effect on quality of life. Acta Obstetricia et Gynecologica Scandinavica. 2013;92(1):109-15.

112. Kumar R, Ooi C, Nicoll A. Five year follow-up of women with obstetric anal sphincter injury. Journal of Obstetrics and Gynaecology. 2010;30(1).

113. Pollack J, Nordenstam J, Brismar S, Lopez A, Altman D, Zetterstrom J. Anal incontinence after vaginal delivery: A five-year prospective cohort study. Obstetrics and Gynecology. 2004;104(6):1397-402.

114. Roos AM, Thakar R, Sultan AH. Outcome of primary repair of obstetric anal sphincter injuries (OASIS): does the grade of tear matter? Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology. 2010;36(3):368-74.

115. Mahony R, Behan M, Daly L, Kirwan C, O'Herlihy C, O'Connell PR. Internal anal sphincter defect influences continence outcome following obstetric anal sphincter injury. American Journal of Obstetrics and Gynecology. 2007;196(3):217.e1-.e5.

116. Cartwright A. Who responds to postal questionnaires? Journal of epidemiology and community health. 1986;40:267-73.

117. McHugh S, Collins M, Perry I. Trying to Balance Quality: Can We Assume that Improving the Quality of Care Delivery also Improves Quality of Life? . Journal of Clinical Metabolism & Diabetes. 2010;1(2):35-42.

118. Elm Ev, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. Strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. BMJ. 2007;335(7624):806-8.

119. Saranovic D, Barisic G, Krivokapic Z, Masulovic D, Djuric-Stefanovic A. Endoanal ultrasound evaluation of anorectal diseases and disorders: Technique, indications, results and limitations. European Journal of Radiology. 2007;61:480-9.

120. Karmarkar R, Bhide A, Digesu A, Khullar V, Fernando R. Mode of delivery after obstetric anal sphincter injury. European Journal of Obstetrics Gynecology and Reproductive Biology. 2015;194:7-10.