



**UNIVERSITY OF  
PLYMOUTH**

PEARL

PHD

**Exploring factors that influence women's self-management of rectal emptying difficulty**

Eustice, Sharon

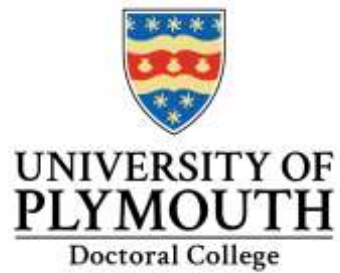
**Award date:**  
2022

*Awarding institution:*  
University of Plymouth

[Link to publication in PEARL](#)

## **Copyright Statement**

*This copy of the thesis has been supplied on condition that anyone who consults it is understood to recognise that its copyright rests with its author and that no quotation from the thesis and no information derived from it may be published without the author's prior consent.*



**Exploring factors that influence women's self-  
management of rectal emptying difficulty**

by

**Sharon Eustice**

A thesis submitted to the University of Plymouth  
in partial fulfilment for the degree of

**DOCTOR OF PHILOSOPHY**

School of Nursing and Midwifery

**January 2022**

## **Acknowledgements**

I am deeply grateful to Professor Bridie Kent, Professor Ruth Endacott and Dr Alison James, my supervisors, for their essential counsel, unwavering support, and patience throughout my PhD studies. Their vast knowledge and wealth of experience have aided me throughout this academic journey. I'd also like to express my gratitude to NHS Innovations, the MDTi and the participants of the research. I would like to express my gratitude to my clinical colleagues, especially Helen Lyndon, Consultant Nurse for her encouragement and expertise. It is because of their generous support that my studies have been possible. Finally, I would like to thank my husband and family for their belief in me. It would not have been possible without their wonderful encouragement and understanding over the last few years.

## **Author's Declaration**

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Doctoral College Quality Sub-Committee.

Work submitted for this research degree at the University of Plymouth has not formed part of any other degree either at the University of Plymouth or at another establishment.

## **Publications (or public presentation of creative research outputs)**

Eustice, S., Endacott, R., Morris, J., Shankar, R. & Kent, B. 2018. Women's experiences of managing digitation: do we ask enough in primary care? *JRSM Open. August 2018. doi:10.1177/2054270418783616*

Eustice, S., James, A., Endacott, R. & Kent, B. 2020. Identifying the health care initiated and self-initiated interventions used by women for the management of rectal emptying difficulty secondary to obstructive defaecation: a scoping review protocol. *JBI Evidence Synthesis: February 2021 - Volume 19 - Issue 2 - p 491-498 DOI: 10.11124/JBIES-20-00026*

## **Presentations at conferences**

Annual Research Event 2018 – Plymouth Guildhall, 15 March 2018

Poster presentation “Women’s experiences of managing digitation:  
do we ask enough in primary care?”

Incontinence: The Engineering Challenge XI 28-29 November 2017 Institution  
of Mechanical Engineers, London

Oral presentation “Does a person-centred device make a positive difference to  
women’s experiences of managing digitation?”

Postgraduate Society Research Showcase 5 December 2016, 1300 - 1630  
Plymouth University

Poster presentation “An alternative to digitation: a report on Femmeze®”

Word count of the main body of thesis: 50,595

Signed:

A handwritten signature in black ink, appearing to read "Sharon E. Price". The signature is written in a cursive style with a large initial 'S'.

Date: 31<sup>st</sup> January 2022

## **Declaration of Conflicting Interests**

The patient-centred device called Femmeze® is a central element of this thesis. Femmeze is manufactured by the Medical Devices Technology International (MDTi) and an invention by Sharon Eustice. Royalties have been collected by the National Health Service (NHS, UK) and contribute to improving healthcare. Sharon Eustice has not received any financial reward. Intellectual property of Femmeze® is held by the MDTi. Femmeze® is available to self-purchase online within the United Kingdom (UK) and other countries.

## **Abstract**

**Sharon Eustice**

### **Exploring factors that influence women's self-management of rectal emptying difficulty**

#### **Aim**

The aim of this study was to pragmatically investigate a vital element of bowel function, where emptying the rectum is difficult in women, usually because of obstructive defaecation, secondary to rectocele.

#### **Background**

Rectal emptying difficulty in women is a sign of obstructive defaecation, which affects about one out of every ten women and can increase with age. Rectal emptying difficulty has a mostly unknown influence on women, and it is frequently a hidden issue. Women's self-management alternatives are underappreciated, as is the impact of such interventions on their quality of life. Despite the magnitude of the problem and its influence on women's lives and health care, non-surgical alternatives have received little attention.

#### **Methods**

The research consisted of an exploratory phase of nine self-selecting women who had self-purchased the patient-centred device. This was followed by a mixed-method study, using an explanatory sequential approach with 35 female participants, recruited via secondary care outpatient clinics. The participants completed a composite questionnaire before and after an eight-week



intervention using a patient-centred device, an alternative to using their fingers to help empty the rectum. The questionnaire comprised of a quality-of-life instrument (ICIQ-Vaginal Symptoms and Obstructed Defaecation Syndrome Questionnaires), bowel diary recordings and participant feedback on using the device. The majority of the same participants (n=26) subsequently took part in a semi-structured interview.

## **Findings**

The exploratory phase provided preliminary insight into self-initiated use of the patient-centred device, suggesting an improved quality of life and a reduction of symptoms. The questionnaire result from the mixed methods study identified that the patient-centred device helped participants reduce the need to use their fingers ( $z=-2.844$ ;  $p=0.004$ ) and offered the participants a better lifestyle. There was a significant reduction in difficulties to evacuate, digitation to evacuate, the feeling of incomplete evacuation, straining to evacuate and lifestyle alteration, all below the threshold of significance ( $P=0.05$ ). Medication to evacuate, returning to the toilet to evacuate and time needed showed no difference. The sense of incomplete emptying before and after using the device was significant ( $z=-2.646$ ;  $p=0.008$ ) as was the feeling of being blocked, which improved following the use of the device ( $z=-3.317$ ;  $p=0.001$ ). Stool consistency did not change before or after using the device. Twenty-four participants (68.5%) completed the Patient Global Impression of Improvement question post-intervention. Overall, 16 participants (66.7%) reported that the device was better than not using it. Using framework analysis interview findings revealed six themes, knowledge, consequences, finding a solution, psychological impact,

coping, and physical impact. The mixed-methods study showed that the patient-centred device was acceptable to participants.

## **Conclusions**

The research study has contributed to the existing body of knowledge on rectal emptying difficulty in women. Firstly, the effectiveness of a patient-centred device for women with rectal emptying difficulty to use as an alternative for using their fingers to help empty the rectum. Furthermore, it offers an additional conservative measure option within healthcare provision. Second, the participants' lived experiences can help healthcare professionals, such as women who report with a bowel problem, learn more about rectal emptying difficulty, which can improve quality of life and prompt access to care. The research has strengthened the feasibility for further investigation via a randomised controlled trial.

## Table of Contents

Copyright Statement .....	i
Title page .....	ii
Acknowledgements .....	iii
Author's Declaration.....	iv
Declaration of Conflicting Interests .....	vi
Abstract.....	vii
Table of Contents.....	x
List of Figures .....	xx
List of Tables.....	xxii
Glossary of Terms.....	xxiv
Chapter 1 Introduction .....	1
1.1 Pathophysiology of bowel function.....	2
1.2 Psychology of bowel function.....	5
1.3 How the research transpired.....	9
1.4 Thesis aim .....	11
1.5 Research questions .....	12
1.6 The researcher position .....	14
1.7 Definition of terms.....	17
1.8 The significance of the study .....	19
1.9 Thesis structure .....	20
1.10 Summary .....	20
Chapter 2 Innovation and product development .....	22

2.1	Introduction .....	22
2.2	Innovation and invention .....	22
2.3	Nursing contribution with invention and innovation .....	26
2.4	Complex interventions .....	30
2.5	Feasibility .....	34
2.6	Applying a metaphor .....	36
2.7	Summary .....	38
Chapter 3 Scoping Review .....		40
3.1	Introduction .....	40
3.2	Abstract.....	41
3.3	Background.....	42
3.4	Review question .....	46
3.5	Inclusion criteria.....	46
3.5.1	Participants .....	46
3.5.2	Concept.....	47
3.5.3	Context.....	47
3.5.4	Types of sources .....	47
3.6	Methods.....	48
3.6.1	Search strategy .....	48
3.6.2	Study selection.....	49
3.6.3	Data extraction .....	49
3.6.4	Data analysis and presentation .....	50

3.7	Results.....	50
3.7.1	Study inclusion .....	50
3.7.2	Characteristics of included studies .....	52
3.7.3	Review findings .....	52
3.8	Discussion .....	56
3.9	Conclusions .....	58
3.10	Summary .....	60
Chapter 4 Theoretical position .....		61
4.1	Introduction .....	61
4.2	Theoretical positioning .....	62
4.3	Chronology of bowel mastery .....	64
4.3.1	Social learning theory.....	66
4.3.2	Self-efficacy.....	69
4.3.3	Coping behaviour .....	71
4.4	Development of a Preliminary Conceptual Framework.....	75
4.5	Central concepts of the conceptual framework .....	76
4.6	Filling the Knowledge Gap .....	77
4.7	Summary .....	78
Chapter 5 Design and Methods .....		79
5.1	Introduction .....	79
5.2	Ontology and epistemology .....	80
5.2.1	Ontology.....	80
5.2.2	Epistemology.....	81

5.3	Implementation of evidence into practice.....	82
5.4	Mixed methods and Pragmatism .....	84
5.5	Implementation sequence and mixing .....	87
5.6	Study aim and objectives.....	88
5.6.1	Aim.....	88
5.6.1.1	Supplementary first aim (Exploratory):.....	89
5.6.1.2	Supplementary second aim (Phase 1):.....	90
5.6.1.3	Supplementary third aim (Phase 2):.....	90
5.7	Exploratory Phase .....	90
5.7.1	Sample selection and recruitment.....	93
5.7.2	Data Collection.....	94
5.7.3	Data analysis.....	95
5.8	Phase 1: Quantitative.....	95
5.8.1	Design.....	95
5.8.2	Phase 1 Research question .....	96
5.8.3	Sample selection and recruitment.....	96
5.8.6	Patient-centred device.....	100
5.8.7	Data Collection.....	101
5.8.8	Data Analysis .....	106
5.8.9	Adverse events/patient safety .....	108
5.8.10	Public and Patient Involvement (PPI).....	108
5.9	Phase 2: Qualitative.....	110

5.9.1	Phase 2 Research question .....	110
5.9.2	Sample selection and recruitment .....	110
5.9.3	Data Collection.....	111
5.9.4	Data Analysis .....	113
5.10	Ethics Considerations.....	117
5.10.1	Beneficence and Non-Maleficence .....	118
5.10.2	Informed consent .....	118
5.10.3	Investigator role .....	119
5.10.4	Public and Patient Involvement (PPI).....	120
5.11	Establishing Rigour.....	120
5.11.1	Phase 1 Quantitative: Validity and Reliability .....	120
5.11.2	Phase 2 Qualitative: Trustworthiness.....	122
5.11.2.1	Credibility .....	122
5.11.2.2	Transferability .....	123
5.11.2.3	Dependability .....	124
5.11.2.4	Confirmability .....	125
5.12	Summary .....	127
Chapter 6 Results: Exploratory Phase .....		129
6.1	Introduction .....	129
6.2	Description of the sample .....	129
6.3	Findings .....	130
6.5	Summary .....	137

Chapter 7 Results: Phase 1 .....	139
7.1 Introduction .....	139
7.2 Aims and Objectives .....	139
7.3 Demographic data .....	140
7.3.1 Sample characteristics .....	140
7.4 Participant-reported outcome data.....	140
7.5 ICIQ-Vaginal Symptoms quality of life analysis.....	144
7.6 Obstructed Defaecation Syndrome analysis .....	144
7.7 Bowel diary .....	145
7.7 Patient Global Impression of Improvement analysis .....	147
7.8 Patient-centred device feedback.....	148
7.8.1 Preference.....	148
7.8.2 Self-reported effectiveness.....	148
7.8.3 Ease of use .....	149
7.8.4 Place of use .....	149
7.8.5 Convenience .....	149
7.9 The ‘feel’ of the device and participant suggestions .....	149
7.10 Withdrawals .....	151
7.11 Patient Participation Involvement (PPI) .....	151
7.12 Summary .....	153
Chapter 8 Results from Phase 2.....	155
8.1 Introduction .....	155
8.2 Aims and objectives.....	155



8.3	Description of participants.....	155
8.4	Interview process and characteristics .....	156
8.5	Framework analysis .....	156
8.6	Themes from the interview data.....	157
8.7	Coding agreement .....	158
8.8	Theme: Knowledge.....	158
8.8.1	Communication and information.....	158
8.8.2	Metacognitive knowledge .....	159
8.8.3	Factual knowledge .....	160
8.9	Theme: Consequences.....	160
8.9.1	External locus of control .....	161
8.9.2	Internal locus of control .....	162
8.10	Theme: Finding a solution .....	163
8.10.1	Diagnostics .....	163
8.10.2	Interventions .....	164
8.10.3	Surgery .....	165
8.11	Theme: Psychological impact.....	165
8.11.1	Emotional factors .....	166
8.12	Theme: Coping.....	168
8.12.1	Tolerance .....	168
8.12.2	Mastering .....	169
8.13	Theme: Physical impact .....	169

8.13.1	Internal factors .....	170
8.13.2	External factors .....	170
8.14	Summary .....	171
Chapter 9	Discussion .....	172
9.1	Introduction .....	172
9.2	Seeking to understand .....	173
9.3	Self-management .....	175
9.4	Conservative measures .....	177
9.5	Medical device development.....	178
9.6	An alternative option to usual care.....	181
9.7	Feasibility .....	190
9.8	Conceptual Framework.....	196
9.8.1	Applying the framework to inform healthcare delivery .....	200
9.8.2	Benefits and limitations of the framework.....	201
9.9	Limitations of the research .....	203
9.9.1	Bias .....	203
9.9.2	Lack of previous research studies .....	204
9.9.3	Time constraints.....	204
9.9.4	Issues with sample size and recruitment.....	204
9.9.5	Data collection by questionnaire .....	206
9.9.6	Data collection by interview .....	208
9.9.7	Interpretation of results.....	209

9.9.8	Loss of contact with PPI group .....	209
9.10	Summary .....	210
Chapter 10	– Conclusions.....	211
10.1	Introduction.....	211
10.2	Overview.....	212
10.3	Summary of the key findings .....	212
10.4	Lessons learned along the way .....	214
10.4.1	Invention and innovation .....	214
10.4.2	Methodological lessons.....	214
10.5	Contribution to Clinical Practice.....	216
10.6	Contribution to Knowledge.....	217
10.7	Implementation of evidence.....	217
10.8	Recommendations for practice and future research .....	218
10.8.1	Clinical practice.....	218
10.8.2	Research.....	219
10.8.3	Product design and availability.....	219
10.9	Summary .....	220
Bibliography	.....	221
Appendix 1:	Search strategies .....	243
Appendix 2:	Studies ineligible following full-text review .....	250
Appendix 3:	Data extraction instrument .....	253
Appendix 4:	Characteristics of included studies.....	254
Appendix 5:	Concept Map.....	258

Appendix 6: Product Evaluation Questionnaire.....	259
Appendix 7: Are you bothered by your bowel poster.....	267
Appendix 8: Patient Information Leaflet .....	268
Appendix 9: Consent Form .....	273
Appendix 10: Patient-centred device user guide.....	274
Appendix 11: Bowel diary .....	276
Appendix 12: Device Feedback Questionnaire .....	278
Appendix 13: Participant Guidance Note .....	286
Appendix 14: Interview schedule .....	287
Appendix 15: Proctogram Measurements.....	288
Appendix 16: Constipation standard pathway .....	259
Appendix 17: Evaluation form findings.....	260
Appendix 18: Framework Matrix of themes, categories and codes.....	264
Appendix 19: Extract from the Framework Matrix .....	265

## List of Figures

Figure 1.1: Anatomy of the bowel (Purchased from iStock <a href="https://www.istockphoto.com">https://www.istockphoto.com</a> Accessed: 6 May 2022) .....	3
Figure 1.2: Normal anatomy and rectocele (Purchased from Shutterstock <a href="https://www.shutterstock.com">https://www.shutterstock.com</a> Accessed: 6 May 2022) .....	5
Figure 1.3: Patient-centred device (Source: MDTi) .....	11
Figure 2.1: Strengthening the Role of Nurses in Medical Device Development Roadmap (with permission from Castner <i>et al.</i> 2016) .....	27
Figure 2.2: The Future Inventive and Innovate Nurse Model (with permission from Davis and Glasgow 2020) .....	29
Figure 2.3: Logic model for the introduction of a patient-centred device for women with rectal emptying difficulty (Public Health England, 2018) .....	33
Figure 2.4: Clinical and implementation relationships (with permission from Eldh <i>et al.</i> 2017)) .....	35
Figure 3.1: Search results, study selection, and inclusion process in the scoping review .....	51
Figure 4.1: Bowel mastery linked to theory .....	65
Figure 4.2: Bowel Mastery Conceptual Framework .....	76
Figure 5.1: Explanatory-sequential mixed methods design .....	86
Figure 5.2: Exploratory phase, Phase 1 and 2 .....	87
Figure 5.3: Objectives with the exploratory phase, Phase 1 and 2 .....	89
Figure 5.4: Pre-post intervention design .....	96
Figure 5.5: Recruitment process for Phase 1 .....	99
Figure 5.6: Position of patient-centred device on insertion and its posterior direction on the back wall of the vagina .....	101
Figure 5.7: Number of participants within PPI and non-PPI .....	109

Figure 5.8: Phase 2 interview participants .....	111
Figure 6.1: Numbers of women reporting on effectiveness, ease of use, place of use, and convenience when using the device.....	133
Figure 6.2: Two case reports in the Exploratory Phase .....	137
Figure 8.1: Relationship of themes .....	157
Figure 9.1: Bowel Mastery Conceptual Framework .....	197
Figure 9.2: Bowel Mastery Conceptual Framework - Lived Experience.....	199
Figure 9.3: Implementation framework for rectal emptying difficulty in women (Sarma <i>et al.</i> , 2021) .....	201

## List of Tables

Table 2.1: MRC framework applied to the patient-centred device.....	31
Table 2.2: Tapestry metaphor .....	38
Table 3.1: Health care interventions identified within included scoping review papers.....	53
Table 5.1: Swedburg's six types of exploratory research (Swedberg, 2020).....	91
Table 5.2: Evaluation form questions .....	94
Table 5.3: Eligibility criteria .....	98
Table 5.4: Data collection and analysis.....	107
Table 5.5: Discounted analytical approaches .....	114
Table 5.6: Thematic and Framework Analysis Similarities .....	115
Table 5.7: Strengths and weaknesses for validity and reliability .....	121
Table 6.1: Age, duration of rectocele, and current management .....	130
Table 6.2: Quotes from the women within each of the self-reported domains	136
Table 7.1: Number of participants with children .....	140
Table 7.2: Summary data.....	141
Table 7.3: Age and size of the rectocele .....	143
Table 7.4: BMI and self-reported effectiveness of the patient-centred device.	143
Table 7.5: Participant response for surgery .....	144
Table 7.6: Changes in scores at baseline and post-intervention for the ODS questionnaire using the Wilcoxon Signed-Rank Test.....	145
Table 7.7: Use of laxatives.....	145
Table 7.8: Sense of incomplete emptying at baseline and post-intervention result using the Wilcoxon Signed-Rank Test.....	146
Table 7.9: Feeling blocked at baseline and post-intervention result using the Wilcoxon Signed-Rank Test.....	147

Table 7.10: Patient Global Impression of Improvement (PGI-I) frequency of response from the participants.....	147
Table 7.11: Proctogram rectocele size and effectiveness of the patient-centred device .....	148
Table 7.12: Participants report on the 'feel' of the device.....	150
Table 8.1: Knowledge theme, category, and code .....	158
Table 8.2: Consequence theme, category, and code.....	160
Table 8.3: Finding a solution theme, category, and code.....	163
Table 8.4: Psychological impact theme, category, and code .....	165
Table 8.5: Coping theme, category, and code .....	168
Table 8.6: Physical impact theme, category, and code.....	169
Table 9.1: The TIDieR (Template for Intervention Description and Replication) Checklist (Hoffmann <i>et al.</i> , 2014).....	192
Table 9.2: Feasibility modifications (Gadke <i>et al.</i> , 2021).....	195
Table 9.3: Benefits and limitations of the Bowel Mastery Conceptual Framework .....	203



## Glossary of Terms

Term	Definition	Source
Anorectal manometry	A procedure to assess the mechanical strength of the anal sphincters.	(Sultan <i>et al.</i> , 2016)
Conservative measures	An intervention not involving surgery or medication approaches.	(Bo <i>et al.</i> , 2017b)
Defaecatory dysfunction	Inability to fully empty the rectum of faeces (also referred to as outlet delay constipation or obstructive defaecation)	(ICD10Data, 2022)
Self-reported effectiveness	Where the participant provides their own description and feedback on the use of the patient-centred device using a composite questionnaire.	(Singal <i>et al.</i> , 2014)
Enemas	A medicinal liquid preparation is administered via the rectum to relieve constipation or to empty the rectum when other treatments for constipation have failed.	(BNF, 2022)
Laparoscopic sacrohysteropexy	A sacrohysteropexy is a procedure that uses a strip of synthetic mesh to elevate and retain a prolapsed uterus in place. It can be performed via keyhole (laparoscopic) surgery.	(BSUG, 2017)
Laxatives	A medicinal preparation is taken orally for the relief of constipation.	(BNF, 2022)
Lived experience	A real-life experience that has occurred or is currently occurring.	(McIntosh and Wright, 2019)
Pelvic floor dysfunction	A wide range of symptoms and anatomic abnormalities are caused by faulty pelvic floor muscular function.	(Grimes and Stratton, 2020)
Pelvic floor musculature	A complex muscular structure, primarily responsible for maintaining both pelvic and abdominal organs, working in tandem with the anterior abdominal wall's striated muscle to generate intra-abdominal pressure.	(Janda, 2006)
Pelvic organ prolapse	When one or more of the pelvic organs descend from their usual place and bulge into the vaginal canal. Rectocele is one example of a bulge.	(NHS, 2021b)

Posterior compartment prolapse	The protrusion of the posterior vaginal wall. Commonly referred to as rectal protrusion into the vaginal canal (rectocele).	(Haylen <i>et al.</i> , 2016)
Prolapse symptoms	A feeling of heaviness or dragging sensation inside or near to the vagina.	(NHS, 2021b)
Sacral nerve stimulation	Used for treating severe faecal incontinence resistant to conservative treatment. The procedure involves passing a low-level electric current through selected sacral nerve roots (in the spine) via an electrode.	(NHS England, 2013)
Stoma	A stoma (colostomy) is a procedure in which one end of the colon (part of the bowel) is diverted via a hole in the stomach. A stoma is the name for the opening.	(NHS, 2020)
Suppositories	Solid bullet-shaped preparation is administered via the rectum for the relief of constipation or to empty the rectum when other treatments for constipation have failed (e.g., glycerol or bisacodyl).	(BNF, 2022)
Trans-anal irrigation	A self-administered system whilst sitting over a toilet, to wash out faeces from the rectum and sigmoid part of the bowel. The system uses a rectal catheter with an inflatable balloon, a manual control unit with a pump, leg straps, and a bag to hold water.	(NICE, 2018)
Vaginal hysterectomy	A surgical procedure to remove the uterus through the vagina.	(NHS, 2019)
Vaginal support pessaries	A passive mechanical device is inserted into the vagina to provide support and reduce prolapse symptoms.	(Bugge <i>et al.</i> , 2013)



## Chapter 1 Introduction

Bowel function and the elimination of its waste affect us all. When the bowel functions correctly, it tends to be a low priority in everyday life. Specifically, it can be taken for granted. However, faulty functioning of the bowel (e.g., bloating, cramps, constipation, diarrhoea, soiling, rectal emptying difficulty) can penetrate our sense of autonomy and well-being and become a wretched problem for many. The prevalence of bowel dysfunction in the western world is increasing (Palsson *et al.*, 2020). Reasons can be complex, but lifestyle and the abundance of highly processed foods may account for some of this (Lacy *et al.*, 2016). For instance, irritable bowel syndrome, which is a collection of gastrointestinal symptoms (i.e., bloating, cramps, constipation, or diarrhoea) has been studied across six European countries; 60% of the study group (n=525) experienced severe symptoms, defined as abdominal pain and distention (Tack *et al.*, 2019). However, prevalence rates for lower-income countries are less known, possibly reflecting healthcare access and help-seeking behaviours. Whatever the prevalence, clinical experience acknowledges the depth of distress and suffering for many people, notably women (Bezerra *et al.*, 2014). Although not completely understood why, it is suggested that gender differences may be attributable to sex hormones (Kim and Kim, 2018). Rectal emptying problems affect about one out of every ten women, and this number can rise as women get older (Chatoor and Emmanuel, 2009). Little is known about its impact. This thesis is about improving women's bowel health. Although bowel dysfunction is widely written about (Alexander *et al.*, 2020), their health experiences continue to reveal new clinical problems to be solved. Women with rectal emptying difficulty are suffering

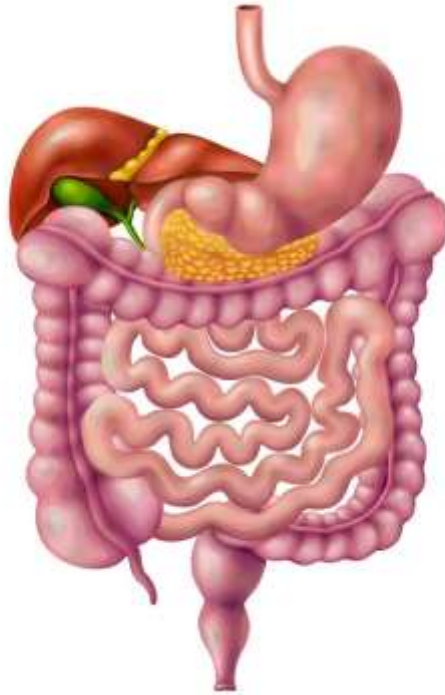
silently. The clinical problem to be revealed and contribute to improving care is rectal emptying difficulty in women.

## **1.1 Pathophysiology of bowel function**

The conditions of inflammatory bowel disease and irritable bowel syndrome have dominated the literature (Blackwell *et al.*, 2020) and understandably so.

Prevalence rates for irritable bowel syndrome can reach 31.6% depending on the country (Sperber *et al.*, 2017) and illuminate the scope of bowel dysfunction.

However, functional bowel disorders are beginning to be exposed as a collective description (Lacy *et al.*, 2016). Functional bowel disorders are defined as those without a physical or metabolic abnormality and diagnosis is nearly entirely based on symptom patterns (Palsson *et al.*, 2020) using Rome diagnostic criteria to facilitate a diagnosis (Simren *et al.*, 2017). Rome criteria were developed by an international group of clinical scientists who generate scientific data and instructional materials to aid in diagnosing and treating gut-brain disorders (Rome Foundation, 2016). This thesis focuses on the large bowel (otherwise known as the colon), including the rectum and anus (Figure. 1.1). Rectal emptying difficulty is not classified as inflammatory bowel disease, irritable bowel syndrome or a functional bowel disorder. It is a secondary to obstructive defaecation disorder. The anatomy and physiology of the bowel enables a deeper understanding.



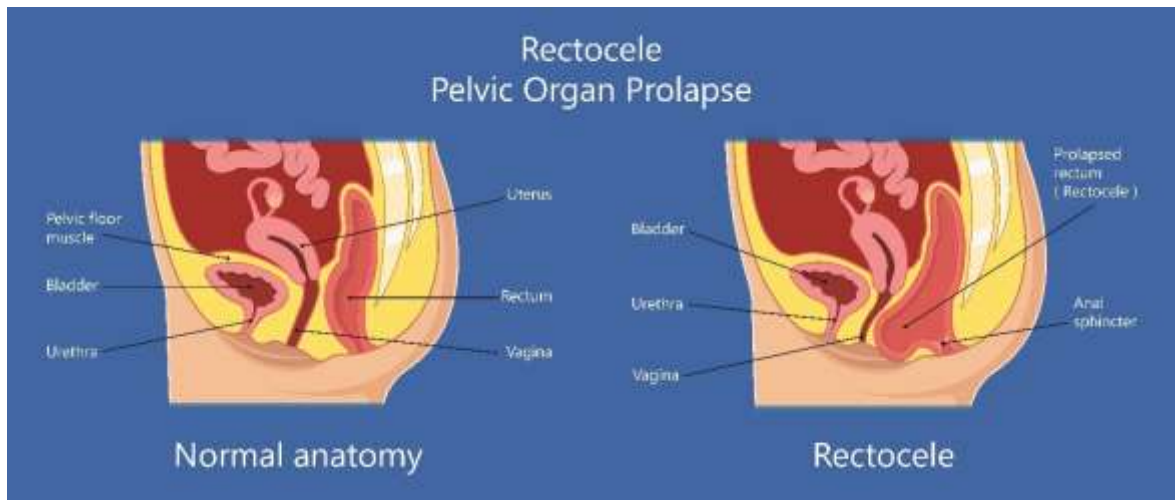
**Figure 1.1: Anatomy of the bowel (Purchased from iStock**

**<https://www.istockphoto.com> Accessed: 6 May 2022)**

The large bowel comprises the ascending, transverse, and descending colon, which feeds into the rectum, supported by a complicated intrinsic and extrinsic nerve supply (Brookes *et al.*, 2009). The colon's three primary functions are absorbing water, electrolytes, managing vitamins, and forming faeces, pushing them towards the rectum for evacuation (Azzouz and Sharma, 2018). A normal transit of formed faeces facilitates the mechanism of bowel control through the colon to the rectum. Normal transit time is suggested to be up to 24 hours and is usually measured via clinical imaging techniques (Bharucha *et al.*, 2019). Faster or slower time can lead to watery or constipated stool, with formed stool being easier to defer. The rectal capacity enables the storage of faeces until the individual is compelled to empty them. Being obliged to empty the rectum is

underpinned by a complex array of sensation, rectal and sphincter contraction, and relaxation at the right time orchestrated by the nervous system (Brookes *et al.*, 2009).

The rectum is a muscular reservoir of low pressure to fill and store faeces (Brookes *et al.*, 2009). Situated below the rectum is the anus, which consists of two sphincters (internal and external), enabling continence via contraction to prevent incontinence of faeces or relaxing to facilitate passage of contents. The levator ani supplies the rectal position and its support, also known as the pelvic floor musculature. Therefore, the rectal function is maximised by the choreography of its structure, anatomical position, innervation, blood supply, and optimum stool consistency (Tillou and Poylin, 2016). Furthermore, cognitive function is critical for an interoceptive response to rectal sensation and managing bodily function (Wittkamp *et al.*, 2018). In early childhood, learning to interpret sensations, respond and manage bowel function is a developmental skill (Uzun, 2020). However, this skill can be disrupted at different life stages. For instance, dementia or other brain pathology affecting cognition can disorder interpretation of rectal sensation, leading to constipation (delay in responding to empty the rectum) and consequently faecal incontinence (Russell *et al.*, 2017). Likewise, derangement to the rectal anatomy impacts the effective evacuation of the stool and leads to trapping (Mustain, 2017). Each colon, rectum, and anus component can be subject to inflammation, disease, or structural disturbances (e.g., obstructive defaecation), with consequential symptoms (Vasant and Ford, 2020) (Figure. 1.2).



**Figure 1.2: Normal anatomy and rectocele (Purchased from Shutterstock <https://www.shutterstock.com> Accessed: 6 May 2022)**

## 1.2 Psychology of bowel function

Accepting and being comfortable expressing our bodily functions has not been encouraged throughout the centuries. For instance, the repulsiveness of human faeces is woven through ancient literature, such as Deuteronomy in the Holy Bible (Carroll and Prickett, 2008).

‘There shall be an area for you outside the camp, where you may relieve yourself. With your gear you shall have a spike, and when you have squatted you shall dig a hole with it and cover up your excrement. Since Yhwh your God moves about in your camp to protect you and to deliver your enemies to you, let your camp be holy; let Him not find anything unseemly among you and turn away from you’. (Deuteronomy 23:13-15) (Bible Gateway, 2022)

Therefore, intertwined throughout society and across generations is the unpleasant factor of bodily waste and the expectation that it will not be spoken about (Meyer and Richter, 2015). Against this backdrop, this research journey has required tenacity, self-directed leadership, passion, and determination because of society’s difficulty when discussing this subject. Goffman introduced the concept of stigma from the psychological impact on an individual (Goffman, 1963).



Although his work was seminal, knowing more about the changes to an individual's life and how to recruit hard-to-reach groups is limited. Therefore, challenges have infused the research journey and facilitated discovery to shape healthcare delivery. Therefore, taking time for reflection and self-examination has enabled increased acknowledgment of the dynamics at play for healthcare, the public, and patients.

Understanding the dynamics requires appreciating normal bowel function, which is seldom reported (Brown *et al.*, 2017). Since the nature of bowel function is integral to everyday life, it rarely becomes a central topic within the scientific literature, which is contrary to abnormal bowel function (Blackwell *et al.*, 2020). Helping to set the scene for what is considered normal bowel function, Mitsuhashi *et al.* (2018) shed light on what normal may look like. Their investigation, conducted in the United States, revealed that out of 4,775 male and female participants who completed questionnaires, 95.9% reported between three and 21 bowel movements per week. Factors influencing bowel normalcy were being male, better education, income, and a high fibre diet. Although useful characterisations for understanding normal in bowel function, it opens the need for further investigation. In the absence of normal bowel function, a study by Reinwalds *et al.* (2018) brings into sharp focus what it is like to live with bowel dysfunction. Using qualitative inquiry with 10 participants who experienced rectal resection secondary to rectal cancer, the authors identified three key themes: bowel uncertainty, struggle, and preoccupation with their bowel. These themes affected all parts of their lives and enhanced resilience (Reinwalds *et al.*, 2018).

Thus, normal bowel function appears to be innocuous, implicit, and assumptive, whereas bowel dysfunction can pervade, devastate, and dismantle lives.

The provision of psychological interventions for bowel dysfunction (whatever the presenting condition) has not been a mainstay of healthcare provision (Ballou and Keefer, 2017). Their review on cognitive behavioural therapy, hypnotherapy, and mindfulness-based therapies for irritable bowel syndrome, clearly acknowledges the lack of funding, workforce, and multidisciplinary practice. Keefer *et al.* (2010) developed a self-efficacy measure for inflammatory bowel disease to influence health outcomes, arguing that self-efficacy varies for different life domains.

Therefore, an individual may have high self-efficacy within their career but low self-efficacy in managing a chronic illness. Inability to transfer from one self-efficacious position to another is supported by other authors who classify self-efficacy as general or task-specific (Yeo and Neal, 2013). General self-efficacy relates to an individual's perception of their ability to perform across a wide variety of situations. In contrast, task-specific efficacy refers to perception in the ability to perform specifically to a situation. However, the discourse of self-efficacy generates opposing opinions and continues to be the topic of interest (Williams and Rhodes, 2016). The relationship of self-efficacy and its contribution to arousing anxiety in an individual has been studied in the educational sciences and is not yet clearly defined (Tahmassian and Moghadam, 2011, Yang *et al.*, 2021). In the healthcare context, clinicians need to be aware of and improve their understanding of human nature. Therefore, selecting the best therapies can be sensitive to individual needs but knowing what is available to offer and for whom are they most suited is imperative. Within the irritable bowel syndrome literature,

Windgassen *et al.* (2017) highlight an exciting concept, treating illness-specific anxiety is likely to have better treatment outcomes than focusing on general anxiety. Thus, focusing a spotlight on the brain-gut axis.

The relationship between the brain and the gut has held fascination over the years. Hormonal, immunological, and neural pathways are an enigmatic bidirectional interplay that is not yet fully understood (Weltens *et al.*, 2018, Mukhtar *et al.*, 2019). However, this interplay is considered integral to gut health and cognitive function. For example, signalling disorders along the pathways may culminate in various problems (e.g., eating disorders, inflammation, anxiety, neurodegenerative and autoimmune conditions). On closer examination of the mental health literature, a narrative review (Bioque *et al.*, 2020) looking at microbiota effect on mood disorders, such as schizophrenia, identifies scarcity of evidence in this field. Their suggestion of investigating the use of prebiotics, probiotics, and faecal transplantation as a “cognitive enhancer” is compelling (Bioque *et al.*, 2020, p.1). In sum, the delicate balance of signalling may easily be upset by a weak microbiota.

Microbiota is a term used to collectively describe the millions of healthy bacteria that flourish in the gut (and other parts of the body) and are considered key in the communication between the brain and the gut (Thursby and Juge, 2017).

Depletion of healthy bacteria, for instance, from antibiotic use or poor diet, is of interest in academia and contemporary society. The use of prebiotics and probiotics to maximise gut health is often seen in wellbeing communities and is gradually navigating its way into healthcare practice. Prebiotics are non-digestible

dietary foods, and probiotics are living microorganisms, and when consumed, they contribute to the gut microbial flora of the host, resulting in health benefits (Liu *et al.*, 2019, Camilleri, 2021). Despite the scepticism of pre- and probiotics, evidence is gathering pace to understand what they can offer. In their systematic review of pre- and probiotic use for depression and anxiety, which included 34 eligible clinical trials, Liu *et al.* (2019) found no difference in the use of prebiotics against placebo and a significant effect for probiotics. According to Cryan *et al.* (2019) the possible contribution of microbiota across health conditions is yet to be acknowledged as a general recommendation. Microbiotic health can be problematic because of individual gut differences. Nevertheless, they stressed the importance of focusing on foods as a significant contributor. Overall, research is lacking to offer conclusive evidence. Evidence does exist within the irritable bowel syndrome literature (Diop *et al.*, 2008). Diop *et al.* (2008) found a positive response to probiotic intervention within an intervention group of 31 people with irritable bowel syndrome compared to a control group of 33 people who received a placebo. Stress-related abdominal pain, nausea, vomiting, and flatulence improved in the intervention group. Rectal emptying difficulty is not directly influenced by microbiotic health due to its anatomical nature. Nevertheless, understanding the pathophysiology and psychology of bowel function facilitates the recognition of clinical symptoms and how best to resolve them. These can motivate further research inquiry, which was the case with this research. Therefore, it is important to also understand the positionality of the researcher.

### **1.3 How the research transpired**

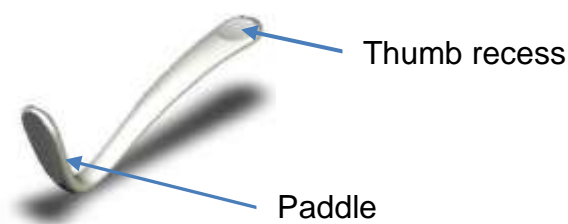
Clinical problem solving occurs in everyday practice for healthcare professionals (HCP). Problems emerging in clinical practice may or may not be straightforward

to solve, based on various factors, including the knowledge and skill of the HCP. Thus, the translation of educational preparation into clinical practice needs to be made explicit and continues a debate (Lehane *et al.*, 2019). Therefore, HCP responsibility for continuing professional development (CPD) is a fundamental underpinning of every patient encounter and can nourish curiosity for clinical problem-solving. Failure to embed knowledge and skill via CPD into working with patients is not only in breach of the professional code (NMC, 2018) but misses an opportunity for improving and innovating practice. Consider the following description of a patient encounter which was a familiar presentation in the clinic setting:

*The woman sat in a blue vinyl chair in a clean, but characterless clinical room trying to find the words to explain her problem. On looking into her lap, she appeared to be studying her hands, which were clamped tight together. After what seemed to be a long silence, she described in a quiet voice the need to put her fingers 'there' to help her stool come out. With gentle coaxing, she allowed more words to flow, and her hands appeared to lose their tight grip on each other. It was the first time she had disclosed what she had to do to herself just to feel comfortable. She used a digitation method, which helps to empty stools from the rectum (Source: author's own words from clinical experience).*

How the woman is feeling and the practical nature of what she needed to do is illustrated by this clinical scenario. Over time, the frequency of similar presentations and women's stories led to developing a practical idea to help. The idea evolved into a solution and thus started the invention and innovation journey. Although the literature on obstructive defaecation (ODS) and its consequences has been gathering pace (Tan *et al.*, 2020), but knowing how women cope has

received little attention. Thus, the lived experience for women who must cope with rectal emptying difficulty remains largely unknown. In this thesis, the problem and one solution to difficulty emptying the rectum, which can lead to self-digitation, will be evaluated. This evaluation will focus on two components. Firstly, the effectiveness of a novel patient-centred device to improve self-management of rectal emptying as an alternative to self-digitation, which is the most used approach. Secondly, the lived experience for women who experience difficulty emptying their rectum will be explored. The invention of the patient-centred device pioneered this research. The patient-centred device is a Class 1 registered medical device designed for single-patient use. It has been developed to provide a clean and dignified alternative for women to self-manage their condition discreetly and confidently. The device is hand-held and features an L-shaped angled paddle inserted into the vaginal canal during defaecation (lubricated with a water-based gel) (Figure 1.3). Using directional pressure on the vaginal back wall, rectal emptying can be helped.



**Figure 1.3: Patient-centred device (Source: MDTi)**

#### **1.4 Thesis aim**

The extent of the clinical problem and improving care for women with rectal emptying difficulty guided by pragmatic research is reported in this thesis.

Comfortable and complete rectal emptying is a vital element of bowel function (Mitsuhashi *et al.*, 2018). Although taken for granted, achieving mastery of bowel

health has long been understood as underpinned by role modelling for toileting training in childhood (Bandura, 1977b), an individual's belief system in looking after themselves (Bandura, 1977a), and how they cope in adverse situations (Lazarus and Folkman, 1987). Their work continues to have current relevance and thus helps explain the complexity of bowel function against a backdrop of what can seem to be a simple fact of human life. Anticipated new and emerging technologies for bladder and bowel incontinence do not include any suggestions for rectal emptying difficulty or its consequences (NIHR Horizon Scanning Centre, 2014). Therefore, this research focussed on an untested, patient-centred device, which had been developed to help women who have obstructive defaecation, manage their rectal emptying difficulty more effectively and satisfactorily than their usual methods. Furthermore, the research aimed to understand what the lived experience is like for women who have trouble emptying their rectum due to obstructive defaecation, secondary to rectocele. In sum, the research investigates usability of the device in combination with user experience, which is considered better than either alone (Bitkina *et al.*, 2020). Consequently, the findings will provide clinical benefit for women and help translate new knowledge into healthcare service delivery, by revealing a tapestry of lived experience.

## **1.5 Research questions**

The research questions answered are:

1. Does the patient-centred device help women who have rectocele, manage obstructive defaecation more effectively and satisfactorily than their usual methods?
2. What is the lived experience like for women who experience difficulty emptying their rectum because of obstructive defaecation secondary to rectocele?

The overall aim of this research was to explore factors that influence women's self-management who have trouble emptying their rectum due to obstructive defaecation, secondary to rectocele. The research design is pragmatic and has several phases; an initial exploratory phase was conducted to inform and help shape the design, followed by a mixed-method approach, using a composite questionnaire and semi-structured interviews, adopting an explanatory sequential design (Cresswell, 2013). Thirty-six women, from a rural county in England, were recruited.

The research offers a pioneering contribution to knowledge via the in-depth study of a hidden world for those women with bowel dysfunction experience.

Furthermore, bestowing innovation in the form of a novel patient-centred device for women in the United Kingdom and beyond. The invention of the device drives research, necessary to enhance women's self-confidence and autonomy with bowel mastery. However, in the context of difficulty with emptying the rectum, commonly viewed as distasteful and mainly unspoken, grasping the significance of the problem can be challenging for healthcare, the public, and patients to acknowledge. Lack of acknowledgement risks the clinical problem remaining in the dark.

Social media quotes added a trigger for the research study. For instance, following the self-purchase of the patient-centred device, one woman posted, '*This is a very useful and easy-to-use device, in my experience. Makes a big difference to my daily life*' (Amazon, 2017). Conversely, another post reported its lack of effectiveness '*My physio recommended this, but the design makes no sense*'



(Amazon, 2018). Although real-life anecdotes enlightened the need for the research, the divergence of women's comments formed the trigger to understand more fully what works best to help them manage this distressing condition.

## **1.6 The researcher position**

In the context of this research, human factors (e.g., communication, knowledge) inform the multi-role position, that is the merging of the clinician, researcher, and inventor roles (Maestre *et al.*, 2018). Human factors, according to Maestre *et al.* (2018), are necessary to drive safety and quality in the delivery of patient care. For the research being reported in this thesis, the motivations were altruistic and the desire to improve women's lives was paramount, given the suffering witnessed in clinical practice. However, acknowledging the multi-position role within this research helps comprehend the barriers to seeking the truth about living with an unspoken and stigmatised subject. Clinical supervision and reflective thought allowed the researcher to examine the obstacles and move forward. Without this, healthcare cannot benefit from new knowledge to achieve better patient outcomes. In the context of this researcher, the key obstacle was the multi-role position, which can influence the push and pull of the research journey, whilst simultaneously stimulating and formidable. Reflecting on the research journey acknowledged these competing elements and helped raise awareness for personal and professional development. Taking digitation as an example, preconceived notions suggested there would always be a better alternative. Finger use is proprioceptive (Quaghebeur *et al.*, 2021), which may not be obtained from a device in the same way. For some women, knowing how much directional pressure to apply involves a sense of knowing, and routine treatment may offer

better control. As a result, it's critical to think about how best to obtain this information from study participants.

One particular competing element is being too close to the data because the multi-role position risks a lack of critical appraisal, which draws on the position of bracketing. Bracketing is a method used in qualitative research and originates from the phenomenology tradition (Tufford and Newman, 2012). Preconceptions can contaminate the study process; thus, it is essential to minimise their negative consequences, which bracketing aims to mitigate. Even though this research is rooted in pragmatism, it is necessary to acknowledge bracketing as a process that has guided many researchers. For Gearing (2004), there are six versions of bracketing, each designed for a particular design of qualitative design: idealist, descriptive, analytical, existential, reflexive, and pragmatic. Loosely applied, reflexive (make personal values, background, and cultural assumptions explicit, overt, and obvious), and pragmatic (depends on the researcher's approach and self-identified focus) resonate with this research. Despite the advantages of bracketing, getting too close remains a possibility of human nature. In a qualitative study of 29 criminal researchers investigating the balance between closeness and sustaining critical analysis, the interviews helped to illuminate the challenge and messiness of getting the right balance (Maier and Monahan, 2009). A key message from their study is to embrace the messiness and consider qualitative research for what it is. Therefore, not to be constrained by rules. However, not getting the right balance can jeopardise trustworthiness. The researcher did not bracket for this study and was instrumental in designing and developing a novel patient-centred device to help women with bowel dysfunction.

However, this also created a conflict of interest that had to be addressed as part of this research. The patient-centred device, which is the intervention for the research, is available for purchase and the commercialisation renders a natural caution for possible research funders. Thus, reassurance of professional and personal integrity within the scientific community is vital.

Action learning in this research context can be considered when the researcher and clinician are the same individuals (Marton *et al.*, 2019). Marton *et al.* (2019) raise an important point about 'what is to be learned' (p.481), which reinforces the opportunity for exploratory and investigative work. Identifying a knowledge gap in particular, makes it easier to take action to close the gap (Preye Robert, 2020). The knowledge gap in this context refers to what is not known about rectal emptying difficulty in women. Therefore, taking action to narrow the gap draws attention to alternative options to help women manage and understanding how they live with it. Although distinguishing the difference between a knowledge and research gap is unclear in the literature (Preye Robert, 2020, Ule and Idemudia, 2018), the research helps serve to fill the knowledge gap. Facilitating this, the implementation science perspective provides a useful perspective. This perspective proposes that the successful transfer of knowledge into practice benefits from understanding how the implementation is best achieved. For instance, the 'Promoting Action on Research Implementation in Health Services' (PARiHS) framework (Kitson *et al.*, 2008) has three components (evidence, context, and facilitation), which can serve as factors to consider for effective integration. In this thesis, the successful implementation of a patient-centred device into the clinical setting was a fundamental aim so that women could access

an alternative solution to digitation. A specific strength of the PARIHS framework is including the patient experience, which other models, theories, and frameworks do not always address (Nilsen, 2015). Although the thesis is not structured on this framework, it is important to acknowledge its existence and it subsequently influenced the development of an implementation framework for rectal emptying difficulty in women.

## **1.7 Definition of terms**

This section includes obstructive defaecation syndrome, rectocele, self-digitation, self-management, and the medical device. The Glossary of Terms list other terms used in the thesis.

Difficulty emptying the rectum is usually a consequence of ODS, most usually secondary to rectocele. ODS is defined as being ‘incomplete evacuation of faecal contents from the rectum, straining at stool and vaginal digitations’ (p.15) (Sultan *et al.*, 2016). Rectal emptying difficulty can be related to a type of pelvic organ prolapse (rectocele) where the rectum herniates forward into the vagina, thus obstructing rectal emptying of stool (Mustain, 2017). Rectocele is usually diagnosed via clinical assessment (physical examination), although clinical imaging is often performed (Aubert *et al.*, 2021). Physical examination, on the other hand, is thought to be more predictive of surgery than clinical imaging such as a proctogram (Wallace *et al.*, 2021). Women with a rectocele may resort to digitally (using their fingers) positioning the anatomy to align the rectum for passing stool (commonly known as digitation or splinting) (Sultan *et al.*, 2016). Self-digitation involves using fingers in the vagina to help push out the stool from the rectum or pressure on the perineum or into the rectum to remove stool. The

evaluation of the patient-centred device drew upon the ‘developing and evaluating complex interventions’ framework, which offered a systematic approach and guidance (Craig *et al.*, 2013). Secondly, what the lived experience is like for women will be explored.

Self-management embraces adjusting to medical tasks, modifying life roles and emotional consequences (Corbin and Strauss, 1988). The concept of self-management has witnessed increasing recognition mainly due rising chronic diseases, such as diabetes (Funnell and Anderson, 2004) and arthritis (Buszewicz *et al.*, 2006). Self-regulation (Clark *et al.*, 2001) and social cognition theories (Bandura, 1991) have governed the understanding of self-management. Rather than information giving only to patients, self-management includes a range of behaviours, such as active participation from the individual and problem-solving skills. However, a crucial factor is how a person manages their condition. A proposed underpinning influence on self-management is the mechanism of self-efficacy (Bandura, 1977a), which will be explored further in Chapter 4. Various definitions have emerged over the years, but simply described, self-management is considered the ability of an individual to manage their healthcare condition on a day-to-day basis (Lorig and Holman, 2003).

Scientific integrity aligned with the development of new medical devices has received minimal attention (Kraemer Diaz *et al.*, 2013). Critical to understanding medical device development is understanding the definition. A medical device can include a variety of products and is defined as ‘... means any instrument, apparatus, appliance, software, material or other article, whether used alone or in

combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings' (p.5) (European Union, 1993). Critical to new product development, such as a medical device, is regulation (Racchi *et al.*, 2016). However, aligning regulations with the principles of good practice within research is less explicit, although efforts have been made to develop recommendations (Kretser *et al.*, 2019) to boost scientific integrity. Stakeholders in medical device development involve industry and elements of marketing practice, thus possibility rendering it more challenging to ensure maximum collaboration. Whilst the Medical Research Council guidance provides a valuable framework for medical device development (Moore *et al.*, 2015), there is scope for additional support for the combined clinician, researcher, and inventor. Navigating the complexities of marketing (pre- and post-medical device development) and aligning these with scientific rigour increase the likelihood of mistakes and test the conflict of interest. Consequently, rigour and reassurance throughout a study are critical to facilitate reproducibility and credibility. Given the pragmatism of the research journey, the hallmarks of action learning resonate.

## **1.8 The significance of the study**

Rectal emptying difficulty in women often goes unnoticed, resulting in silent anguish. This study sheds light on the lived experience of women who have problems emptying their rectum due to rectocele-related obstructed defaecation. The study also includes a first-of-its-kind investigation of the patient-centred device, which can be used instead of fingers to empty the rectum. The study's findings provide a helpful reference point for understanding the factors that

influence women's access to healthcare and how health care providers may improve care delivery. Finally, the study's findings are likely to raise awareness of the hidden world of women's suffering and push change in healthcare for women who have trouble emptying their rectum.

## **1.9 Thesis structure**

The following chapters in this thesis report on the research journey. In Chapter 2, the interconnectedness of innovation and invention is explored and the contribution of nursing, setting the scene for the feasibility of the research and introducing a metaphor of tapestry making. Chapter 3 presents a Scoping Review exploring what interventions women use for the management of rectal emptying difficulty secondary to obstructive defaecation. Chapter 4 presents the theoretical positioning and introduces a preliminary conceptual framework. Chapter 5 details the design and methods of the research. In Chapter 6, the exploratory phase results are described. Chapter 7 presents the quantitative results of Phase 1. After that, Chapter 8 presents the qualitative results of Phase 2. Penultimately, Chapter 9 provides a discussion on the findings and revisits the conceptual framework; and finally, Chapter 10 contributes to the thesis conclusions, defining the contributions to clinical practice and knowledge; and makes recommendations for practice and future research.

## **1.10 Summary**

In summary, the research problem, research questions, and researcher position have all been expressed against the backdrop of a considerable clinical problem in this introduction. To offer context for the clinical problem under investigation, pathophysiology and psychology of the bowel have been explored. This thesis

contributes to knowledge and clinical practice through the increased understanding of how women cope with and experience obstructive defaecation; and offers a potential unparalleled medical device as an alternative solution to self-dilatation. The thesis has established the researcher's position of invention because of being instrumental in designing and developing a unique patient-centred device to assist women with bowel disorders. Therefore, Chapter 2 launches the interconnectedness of innovation and invention, which includes the contribution of nursing, setting the scene for the feasibility of the research, and introducing a metaphor of tapestry making.



## **Chapter 2 Innovation and product development**

### **2.1 Introduction**

In this chapter the interdependence of innovation and invention and the role of nursing, expresses the feasibility of the study, and provides a tapestry metaphor will be examined. The invention of a unique patient-centred device within the context of this research journey has helped to unravel a hidden world of women's suffering and how they live with rectal emptying difficulty. The story would not be complete without exploring how invention has made this work possible and how nursing can shape healthcare clinical problems. In the world of metaphor (Bleakley, 2017), this research journey can be likened to tapestry weaving (Clark and Buchanan, 2020). Tapestries have been woven by hand for many centuries, and just as innovation has introduced machine-woven work, humans too have a drive for progression and improvements (Barfield, 2019). Without invention and innovation, the hidden world women experience with rectal emptying difficulty would have remained unexposed. This is particularly pertinent as the researcher is a nurse who has specialised in caring for such women and is the inventor of this device. Therefore, the position of nursing's contribution to invention and innovation is explored.

### **2.2 Innovation and invention**

Where innovation begins and its similarity to the invention need further explanation. Whilst these terms might have been mutually used, there is an argument to suggest critical differences. Damanpour and Evan provide a useful definition: 'Innovation is the implementation of an internally generated or a borrowed idea – whether pertaining to a product, device, system, process, policy,

program or service – that was new to the organisation at the time of adoption. Innovation is a practice, distinguished from invention by its readiness for mass consumption and from other practices by its novelty' (p.393) (Damanpour and Evan, 1984). Although this definition helps clarify, translation into everyday practice is not consistent, especially in the National Health Service (NHS) (Farchi and Salge, 2017). For instance, innovation has not seen NHS infrastructures encouraging clinicians to innovate. That said, a drive for innovation is woven into the NHS Long Term Plan, which promises to '...speed up the path from innovation to business-as-usual' (p.60) (NHS England, 2019). Whilst reassuring, policy and best intentions do not guarantee implementation and spread of new practice across the health community (Thomas *et al.*, 2020). The NHS wants to drive innovation, especially to reduce unnecessary secondary care referrals, which is a pillar of the existing NHS strategy, and this research presents a contribution to providing cost-effective but high-quality healthcare (Duelund-Jakobsen *et al.*, 2015).

Innovation has become a favoured term (Dahlander *et al.*, 2021) and tends to displace or absorb the original invention. Yet an invention does not assume it reaches where it needs to if innovation is not part of the strategy. Moreover, there is an assumption that all innovation is underpinned by good intention. Many inventions and their innovation journey have not always been optimistic or harmless, such as weapons for destruction or unintended consequences such as nuclear accidents (Coad *et al.*, 2021). Hence, innovation strategy needs to respect the merits of doing no harm and shaping knowledge for better healthcare. Trustworthy translation of an invention into a creative journey is critical for patient

safety and quality of care. Implementation science has a rich literature and is defined as the study of methods to enable uptake of an evidenced intervention (Sarkies *et al.*, 2021). Numerous frameworks, such as that by Kitson *et al.* (2008), have helped focus activity onto knowledge shifting into, informing, and then changing behaviour related to practice. Whilst frameworks offer pragmatic and systematic attention to adoption and spreading new ways of working, despite this, the crucial point is that invention and innovation are not mutually exclusive, but instead, they are complimentary. Notwithstanding health professionals' best intentions, the transfer of knowledge into practice is not effective if undertaken passively. Instead, it requires active engagement (Avorn and Fischer, 2010). Literature reveals several methods to do this effectively, but unsurprisingly are contextual in nature and commendable in their portrayal. For instance, Cao *et al.* (2021) used an integrated version of the PARIHS framework (i-PARIHS) to facilitate evidence implementation for intensive care patients to reduce pressure-related injuries. Their findings suggest that the framework assisted with improved care. Likewise, Colldén and Hellström (2018) considered the Consolidated Framework of Implementation Research (CFIR) as a tool for implementing value-based healthcare, for which they suggest improvement to tailor its application. Despite the range of frameworks available, they all offer a systematic method within a complicated journey of change, whatever the healthcare context. Leeman *et al.* (2017) aim to dismantle implementation strategies and offer distinctions by classifying the strategy rather than a one size fits all. What works best should be driven by clinical leadership and effective communication. That said, leadership styles are subject to variation, and despite NHS investment, remain aspirational as the key to implementing evidence-based practice (Grove *et al.*, 2020).

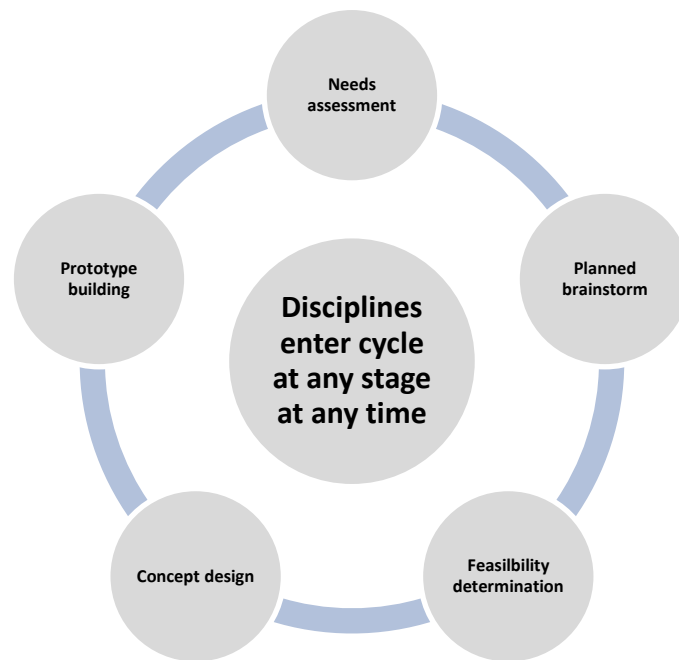
Engagement of healthcare staff requires an understanding of the challenges facing them in practice, such as resistance to change, poor dissemination of evidence, and the lack of educational opportunity. However, acknowledging the difficulty in bringing the idea and the innovation journey to reality is a fundamental first step. Haeussler and Assmus (2021) offer an insight into the challenges that exist for researchers when trying to 'bridge the gap' (p.2) between invention and innovation. Their paper speaks of 'bench to bedside' (p.5) research. However, the research journey presented in this thesis has taken an unconventional route or the opposite approach in that the trajectory has been from the bedside to bench. It stemmed from identifying a clinical dilemma and problem solving via invention, and innovative practice led to broader development and commercialisation. A helpful interpretation from Haeussler and Assmus (2021) is their term of the researcher being a 'translator' (p.2) in bridging the gap.

When translating an invention into an innovative journey, we are reminded of the definition stated by Damanpour and Evan (1984) earlier; invention implies the creation of something new, which makes sense as the starting point for innovation. Thus, innovation is a practice involving the implementation and further development of the invention (Lane and Flagg, 2010). Alternative viewpoints exist within a complex and diverse literature base (Greenhalgh, 2004). In particular, Genus and Iskandarova (2018) argue in their narrative paper that innovation governance has yet to be responsible and reflective, and maybe at the behest of dominant viewpoints, politics, and inhibitive practices. Whatever the characterisation, the cognitive process leading to an invention is multifaceted and

complex. Society has a rich history of examples that have shaped our world today and serve to provide insight into how some of the greatest inventions came to be and transferred into everyday life. For instance, the invention could be likened to the idiom of 'the light bulb moment', whereby a flash of inspiration paves the way to the development of an idea (Cambridge University Press, 2021). Or perhaps it is an insidious incubation of a problem that has been pondered over time and time again until a solution presents itself. Society can be seduced into thinking that the lone mastermind invents. However, Lemley (2011), in his critique of patent law, reminds us that the mastermind's idea is not isolated to an individual, but with teams and co-dependent. Whatever the initiating processes, ideas, and incubation are the fulcrum for many developments and technologies across the centuries. Imagine how Fleming felt when his discovery of penicillin was by accident (Bennett and Chung, 2001), compared to how other inventors have contributed to the world, such as Bell's systematic development of the telephone (Gorman, 1995). The journey towards inventing a device or resource is driven by the individual characteristics of the researcher, such as curiosity, possibility, and creativity. That said, despite these characteristics, ideas might never see the light of day. Nursing practice has produced many examples of ideas or opportunities that may have been missed or uncultivated (Castner *et al.*, 2016).

### **2.3 Nursing contribution with invention and innovation**

The role of nursing in invention and innovation generates an untapped pool of possibilities (Figure 2.1) (Kaya *et al.*, 2016, Castner *et al.*, 2016).



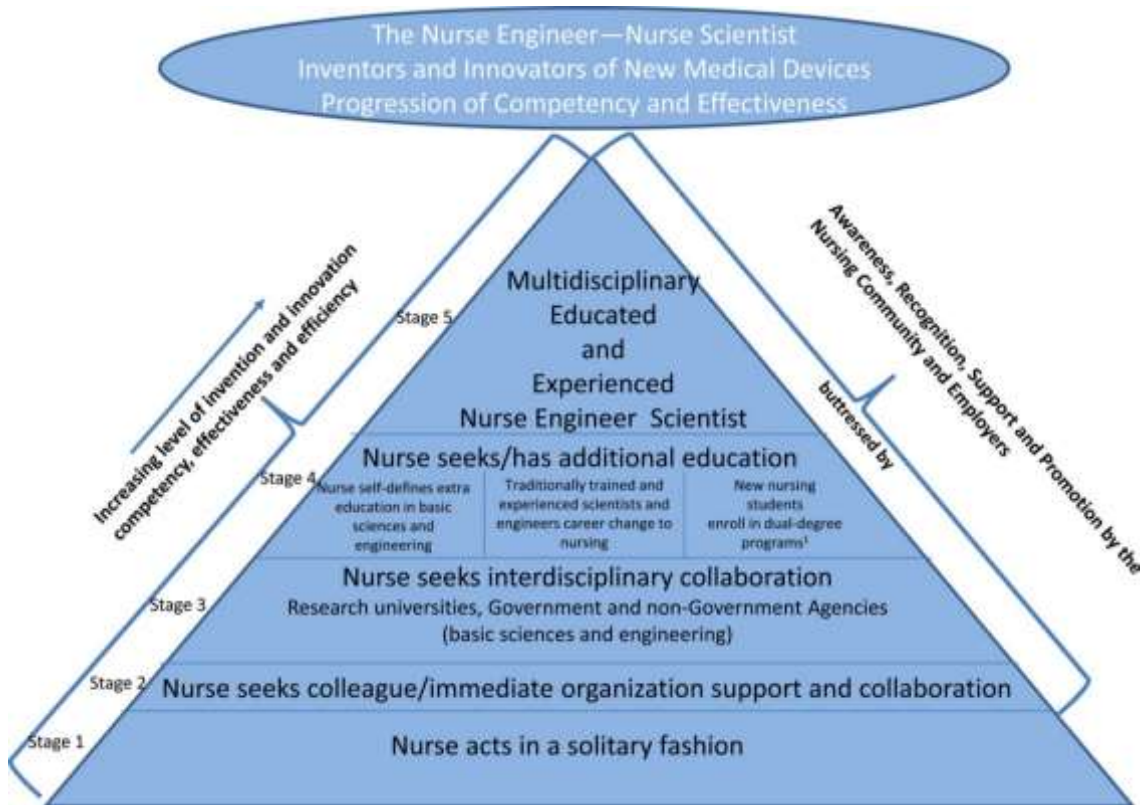
**Figure 2.1: Strengthening the Role of Nurses in Medical Device Development Roadmap (with permission from Castner *et al.* 2016)**

Figure 2.1 shows the cyclical movement through the development phases, which the nurse can enter at any point. Reflecting on the experience, the movement can be moved forward smoothly, stall or move back and forth. Importantly, each phase must receive careful attention to ensure the rigour and trustworthiness of the clinical problem being considered. Nursing provides many opportunities to identify and express clinical issues, especially considering the proximity of nurses to patients and their experiences. However, given the pressures of workload and staffing issues (Kinman *et al.*, 2020), these can form barriers that negatively influence the viability of progressing ideas. Further barriers can include knowledge and skill to navigate the difficult road of making an idea reality. Although policies are in existence to facilitate innovation (AHSN, 2019, NHS, 2021a, NHS England, 2019, Thomas *et al.*, 2020, CQC, 2021), there is a

disconnect, which is possibly underpinned by the inconspicuousness of innovators (Quilter-Pinner and Muir, 2015). Through a qualitative case study investigating organisational adoption of innovation across 12 NHS organisations, the findings revealed that oversight or delay with implementation was due to lack of 'how-to knowledge' (Kyratsis et al., 2012 p.1). Hence innovators bear the responsibility to equip themselves with proficiency in the practical application of new ways of working.

The road towards embedding an invention into everyday practice requires motivation, tenacity, and robust guidance. Facilitating nurses' practice to maximise their contribution to invention and innovation has evolved (Kara, 2016). That said, Davis and Glasgow (2020) shed light on the lack of nursing invention. They identified over 65,000 patented inventions between 1976 and 2019, randomly selecting 100 patents for scrutiny and finding none associated with nursing. Selecting only 100 patents may have missed nursing contributions. There is an assumption that inventions choose the patent route (Blind *et al.*, 2018), which involves a costly process of registering the invention, but some will progress for Community Registered Design (Schlotelburg, 2006), which registers the embodiment of the invention. Reasons for deciding on which route to take may be financial factors (Farchi and Salge, 2017). Refreshingly, however, Davis and Glasgow (2020) propose a model as a pathway that might inform future nursing contribution (Figure 2.2). During self-reflection, the position for this research is between Stage 3 and 4, providing a sense-check of the continuing need for learning and development. Expanding the contribution of nurses to medical device creation is encouraged through recommendations such as

evaluating complex interventions, which was first advocated by the Medical Research Council (MRC) (Craig *et al.*, 2013).



**Figure 2.2: The Future Inventive and Innovate Nurse Model (with permission from Davis and Glasgow 2020)**

Nursing has been exposed to various theories and models of practice (McEwen and Wills, 2017). Whilst theories and models have aimed to explain and give direction, the messiness and complexity of nursing have often been open to scrutiny. More recently, the focus has centred on the individual nurse and what shapes their identity. Bell’s (2021) literature review suggests that nursing identity has yet to emerge from oppression before it can truly realise an identity. Even so, understanding these influencing factors may help shape emerging continuing



professional development. Suppose the cohort of newly qualified nurses who have experienced the same curriculum and be examined against agreed learning objectives. Those nurses will shape health care differently, depending on characteristics and qualities. In another literature review, Rasmussen *et al.* (2018) shed further light on the professional identity of nursing, suggesting that the self, role, and context are necessary to maximise development. Despite the discourse on nursing identity, whilst nursing is currently witnessing turbulence in workload pressures, safe staffing, and emotional toil (RCN, 2019), its future will be influenced by the ability to change and adapt within an increasingly complicated world. Even though the focus of the debate has been on nurses at the forefront of innovation, their role as end-users of innovation should not be forgotten. In a scoping review of 19 papers, Matinolli *et al.* (2020) suggest that nurses tend to be excluded from health and medical device development phases. Therefore, nursing contribution should be exploited at each phase of development to improve healthcare delivery.

## **2.4 Complex interventions**

For this research, the signposting offered by the MRC clarifies that developing an intervention, in this case, a patient-centred device is complex. Complexity in navigating through pre-existing processes and symptoms requires a diverse range of skills (Marjanovic *et al.*, 2020). Understanding how and if the device works in everyday practice requires a detailed framework for rigour and robustness. Elements of the MRC framework includes development, feasibility/piloting, evaluation, and implementation (Craig *et al.*, 2013). The stages of invention and innovation of the patient-centred device reported in this thesis have been

presented by drawing upon this framework to provide clarity and direction (Table 2.1).

**Table 2.1: MRC framework applied to the patient-centred device**

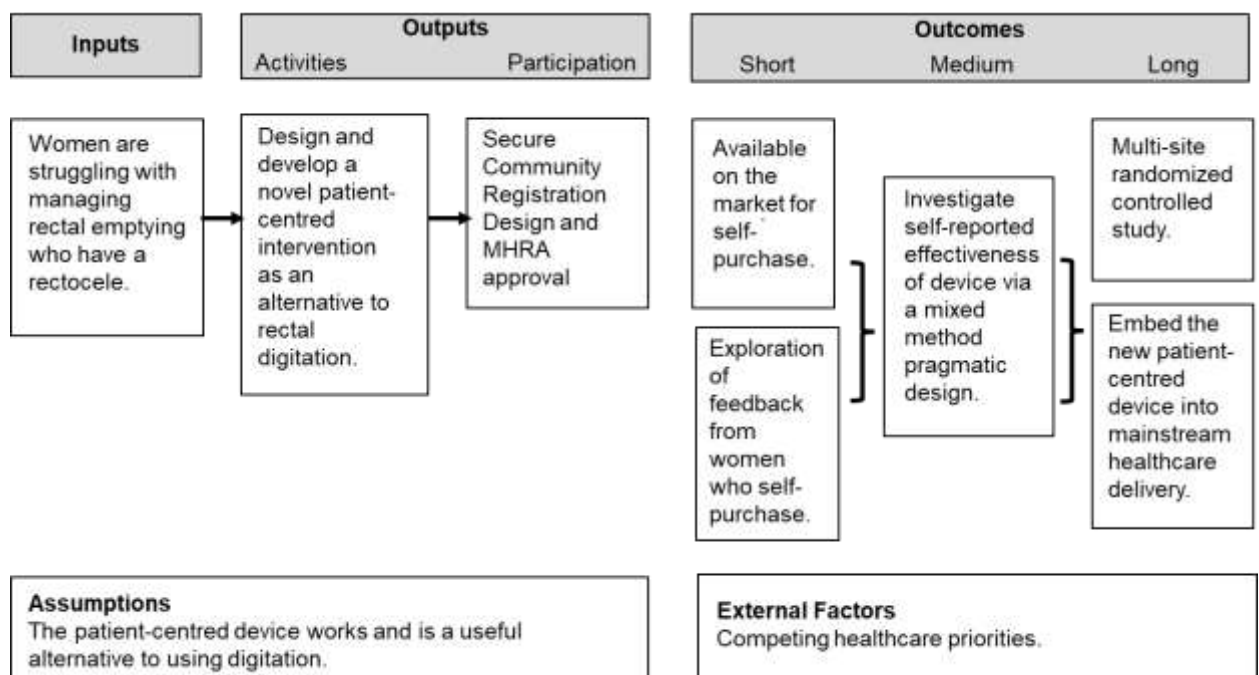
MRC framework elements	Application
Development	A scoping review was conducted because the evidence base had not been established. At the outset, the theory to underpin the development was not clear. However, this has become clearer along the research journey.
Feasibility/piloting	A feasibility approach using mixed methods was considered pragmatic especially considering the novel and untested patient-centred device. Randomisation was not practical or appropriate given the newness of the invention.
Evaluation	Outcome measures were decided upon which yielded an understanding of device self-reported effectiveness and identify barriers to further experimentation post-study. Furthermore, the lived experience of women was considered fundamental to understanding and shaping care delivery.
Implementation	Behaviour changes for both patients and the NHS in the context of improved quality of life and better clinical care pathways.

More recently Moore *et al.* (2015) have reframed this for process evaluation providing a stepwise approach for planning, designing and conducting, analysing, and reporting intervention development. The framework for complex interventions continues to be updated, and more recently to embrace the conditions, implementation and its impact (Skivington *et al.*, 2021). Designing the patient-

centred device was need-driven and is unique in the application (rectal emptying difficulty). Guidance has been developing pace over the years and of note, is Liberman-Pincu and Bitan's (2021) medical engineering application of using FULE. FULE is an acronym for functionality, usability, look-and-feel, and evaluation. Following their testing of FULE via case studies, they suggest that giving attention to each aspect potentially improves the design and implementation. One of the strengths of the FULE framework is the attention to the aesthetic perspective, which resonates with this research. Despite medical device development being multifaceted, the human-centred design mindset is worthy of consideration. Defined as an empathic and intuitive perspective focusing on people and not just the user (Steen, 2011). In other words, stepping back from pre-conceived ideas and suspending arrogance for having a great idea (Design Council, 2022). An inspirational insight to human-centred design is offered by IDEO.org (2015), a global non-profit design company, with focus on innovation within low-income countries. Their compelling approach suggests an emotionally intelligent attitude is fundamental as a foundation for invention and innovation. Whilst there is much to learn from innovation experiences beyond healthcare, the iterative nature of this research requires continuous learning. Notwithstanding the tools, frameworks, and mindset perspectives available to guide research, deciding on the research design required much discussion.

Deciding on the research design for systematically investigating the impact of the patient-centred device was complicated. This arose because the device had already been developed and was in commercial circulation. Yet it was a new device with no underpinning evidence or established position within clinical care. This complexity was discussed with the local research and development team,

exploring different approaches. For example, selecting a controlled design was inappropriate because it assumed knowledge of feasibility for recruitment and retention ease. Translating what was already known about the patient-centred device into a proper design took time. Developing a design needed to consider assumptions that the device would work. Assisting with understanding assumptions, Moore *et al.* (2015) suggest a logic model approach support improved clarity and determining relationships (Figure 2.3). The logic model initially emerged from education (Markham and Aveyard, 2003) and has been adopted as an essential feature in process evaluation (Public Health England, 2018). Figure 2.3 helps to explain the relationships of the inputs, outputs, and outcomes related to women struggling with rectal emptying difficulty.



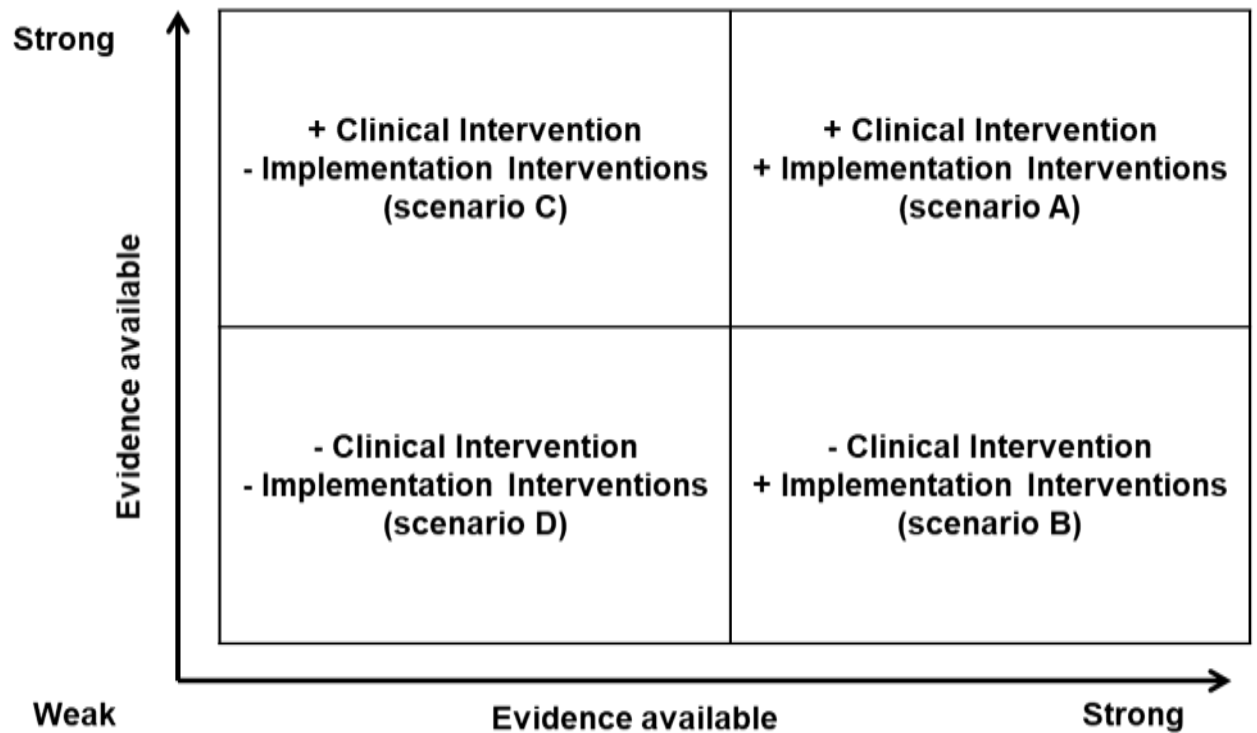
**Figure 2.3: Logic model for the introduction of a patient-centred device for women with rectal emptying difficulty (Public Health England, 2018)**

Therefore, the decision was taken to take a step back and spend time understanding the acceptability of this device to women and determine if the feasibility of wider implementation and roll-out. The feasibility method offers a preliminary investigation into implementing an intervention and informs a future randomised controlled design, where appropriate (Wilson *et al.*, 2015).

## **2.5 Feasibility**

Applying a feasibility approach to this research was a rational consideration. Given the first research question to be answered, 'Does the patient-centred device help women who have rectocele, manage obstructive defaecation more effectively and satisfactorily than their usual methods?' identifying if the patient-centred device works was critical. Giangregorio and Thabane (2015 ) advise that a feasibility study is 'pre-study research that is done to gather pieces of information to formulate the plan for the main study' (p.129). A plea for better definition has been reported in the literature, especially when compared to a pilot study (Arain *et al.*, 2010).

Gathering evidence associated with a new device can be challenging. Such as, what is the best research design to implement, which will find real-world information. This can lead to misunderstanding and confusion due to ambiguity and lack of clarity (Eldh *et al.*, 2017). Eldh *et al.* (2017) offer a sobering awareness of the paucity of examples for the research within this thesis. Figure 2.4 illustrates Scenario D as being the position where this research sat.



**Figure 2.4: Clinical and implementation relationships (with permission from Eldh *et al.* 2017))**

Scenario D (as shown by the twin minus signs) proposes that the evidence base for a clinical intervention has not been established and is thus considered weak. Furthermore, evidence for implementation is weak. Therefore, deciding on the research design took time and deliberation. However, there were examples to draw understanding. Sokol (2017) for instance, investigated a new vaginal bowel control therapy by using it with 13 participants. This involved a vaginal insert and a pressure-regulated pump reducing faecal incontinence. He emphasised that the study was not to provide rigorous outcome data related to the device, but rather it provided an opportunity to gather information for education, training, and future

research. However, it is unclear if the study (Sokol, 2017) positioned itself as feasibility or a pilot study.

Satisfying a randomised controlled trial (RCT) design is not appropriate in a newly developed device domain. That is not to say it should not be exposed to an RCT in due course. Notably, the early stages of medical device invention are dynamic, with twists and turns that may not always be predictable. Thus, for this research, a pragmatic approach was taken since, in this instance, the patient-centred device had emerged from a real-world clinical problem. The device's invention lifted the lid on a world hidden from view, that being the suffering that women experience with rectal emptying difficulty. Although it was not an entirely unknown issue, the subject matter has not fostered enough interest or attention within healthcare science. Therefore, a non-traditional, pragmatic approach was used for this research, which provided insight for the clinician taking a real clinical problem and walking the road to discovery.

## **2.6 Applying a metaphor**

The road of discovery lends itself to attributing a metaphor to the research journey, that of tapestry making, which helps to illustrate and improve coherence and texture. Metaphors are common in figurative speech (Genovesi, 2020), and everyday speech can be saturated with metaphor (Romano, 2017). Bleakley's (2017) definition of metaphor, a 'link between two previously unconnected things, usually acting as a catalyst for a deeper understanding' (p5), is helpful. Metaphors have been used in academic writing to shed light on complex ideas in qualitative research (Carpenter, 2008). Although using a metaphor can sometimes confuse or distort, it can provide a much clearer understanding of what is happening when

used wisely. Kelly (2011) advocates that metaphors add strength to reporting and advise that their use offers a co-existence between two different positions. In this case, the tapestry-making metaphor helps to contribute to more profound meaning and make better sense of the problem. Applying an identity to tapestry making, the tamping of the threads hides the vertical threads from view. Thus, the warp can be likened to an inflexible healthcare system. In contrast, the weft threads form the colours that gradually build-up to create the tapestry's picture and represent the woman's navigation through healthcare. The tapestry can be more colourful on the back as this is usually far less exposed to sunlight. Thus, lifting the lid on women's experiences of rectal emptying difficulty reveals the suffering. Table 2.2 provides details of the concepts prevalent in the women's lived experiences and how these can be applied to the tapestry metaphor. This metaphor will be used throughout the thesis to help illustrate key points.



**Table 2.2: Tapestry metaphor**

<b>Concept</b>	<b>Metaphor</b>
<b>The woman living with rectal emptying difficulty</b>	<b>Tapestry</b> (Mallory S, 2014)
Women displaying composure attending a clinic	Walking through a museum seeing a beautiful tapestry
Enabling the woman to tell her story	Challenging to understand the tapestry meaning and understand at first
Unravelling of the women's experience that may be hidden suffering	A weft-faced plain weave with discontinuous wefts that conceal all its warps
Navigating the healthcare system	Warps and wefts together create the tapestry
Women present at different ages, with different backstories	Wefts come in different colours (collective). The threads are individual but make up a whole
Coping with the problem internally to enable facing the world	Warps are hidden from view – the backbone and support the wefts
Anxiety and low mood	The backside of the tapestry is a jumble of thread, frayed and occasionally knotted
The interconnectedness between the women who have used self-knowledge to cope	The weave of individual threads making up the whole
<b>The researcher</b>	<b>The weaver</b>
Getting inside and understanding the problem	Works facing the back of the tapestry
Seeking the solution	Designing the tapestry in the form of a painting or drawing
Understanding the self-selected options of women (using fingers for rectal emptying)	Tapestries are woven by hand for centuries
Creating a patient-centred device	Machine-woven tapestry innovation
<b>The research</b>	<b>Framework</b>
Mixed methods approach	Loom to hold the tapestry

## 2.7 Summary

Chapter 2 has highlighted the interconnectedness of invention and innovation, and that developing an invention does not guarantee effective implementation via

innovation into healthcare practice. However, recognising the researcher as being a 'translator' in bridging the gap. To close the gap, nurses must make greater use of their profession, presenting a wealth of opportunities to detect and articulate clinical issues. Complex clinical problems need to journey through a stepwise approach for planning, design and conduct, analysis, and reporting as advised by the MRC. Despite this approach, the non-traditional, pragmatic style used for this research recognises the need to understand the feasibility of use as a method to gain insight into the clinician taking a real clinical problem and walking the road of discovery. Richer discovery, deeper meaning, and making better sense of the lived experience of the women with rectal emptying difficulty draws on a tapestry metaphor. The next stage in this journey helps to contextualise the broader aspects of this clinical problem by focusing on what interventions women use for the management of rectal emptying difficulty secondary to obstructive defaecation via a scoping review and is reported in Chapter 3.

## Chapter 3 Scoping Review

### 3.1 Introduction

What interventions are used by women for the management of rectal emptying difficulty due to obstructive defaecation, secondary to rectocele via a scoping review is addressed in this chapter. Given the necessity to characterise and scope the interventions utilised by women, a scoping review was deemed more appropriate for this study than a systematic review. The systematic review aims to critically appraise and summarise the outcomes of available evidence (Munn *et al.*, 2018). The need to dig into the literature and weave together what is known about interventions, is like to the weaver facing the back of the tapestry to see what others may not see. The ability to discover a knowledge gap through facilitating attention to interventions is crucial to this understanding. As a result, this scoping review focuses on what interventions women take to manage rectal emptying problems. Since this research delves into uncharted region in terms of rectal health, it was crucial to expose what is known regarding interventions available. Identifying the health care initiated and self-initiated interventions used by women to manage rectal emptying difficulty used a scoping review approach by means of the Joanna Briggs Institute Scoping Review methodology (Peters *et al.*, 2020). The protocol for this scoping review was published with Joanna Briggs Institute (JBI) Evidence Synthesis:

Eustice S, James A, Endacott R, Kent B. Identifying the health care-initiated and self-initiated interventions used by women for the management of rectal emptying difficulty secondary to obstructive defaecation: a scoping review protocol. *JBI Evid Synth.* 2021 Feb;19(2):491-498. DOI: 10.11124/JBIES-20-00026. PMID: 33027103.

### 3.2 Abstract

**Objective:** This scoping review aimed to identify what interventions are used by women in the management of rectal emptying difficulty due to obstructive defaecation, secondary to rectocele.

**Introduction:** Rectal emptying difficulty is typically a symptom of obstructive defaecation syndrome (ODS). This review was necessary to increase understanding of what interventions are used by women. Increasing understanding of these interventions will inform the development of a specific care pathway to support women living with rectal emptying difficulty.

**Inclusion criteria:** This review considered studies that included adult women (over 18 years of age) living in the community who have experienced difficulty with rectal emptying and who have not had surgical intervention. Exclusion criteria included prolapse surgery and surgical techniques, oral laxatives, vaginal pessaries, cognitive impairment, pregnancy, and those residing in care homes.

**Methods:** The databases searched include MEDLINE, EMBASE, CINAHL, PsycINFO, Emcare, AMED, Web of Science, Scopus, PROSPERO, Open Grey, ClinicalTrials.gov, International Clinical Trials Registry Platform Search Portal, UK Clinical Trials Gateway, International Standard Randomised Controlled Trial Number Registry, JBI Evidence Synthesis, Epistemonikos, Cochrane Library, and gray literature. Studies conducted in English from the initiation of the database to 2019 were considered for inclusion. Two independent reviewers screened the full-text articles for assessment against the inclusion criteria for the review. Any

discrepancies were resolved via discussion. The results were descriptively summarised.

**Results:** The search identified 3117 citations of which five studies met the eligibility criteria. Three studies reported outcomes for biofeedback therapy, and two on pelvic floor rehabilitation. The review concluded that two interventions were identified, which are healthcare initiated. No self-initiated interventions were identified.

**Conclusions:** Whilst this scoping review identified two interventions used by women with ODS secondary to rectocele, limited research was available for this scoping review. Although there is nothing new or innovative to add to current clinical delivery, this review offers a persuasive case for exploring innovation for women with rectal emptying difficulty due to ODS.

### **3.3 Background**

Rectal emptying difficulty in women is typically a symptom of obstructive defaecation syndrome (ODS) (Sultan *et al.*, 2016). ODS has been defined as the 'incomplete evacuation of fecal contents from the rectum, straining at stool and vaginal digitations' (p.15) and is an overarching term to describe pelvic floor disorders (Sultan *et al.*, 2016). Posterior compartment prolapse, one of these disorders, is a type of pelvic organ prolapse where the rectum herniates forward into the vagina (forming a rectocele), obstructing the rectal emptying of stools (Dimitriou *et al.*, 2015). Rectal emptying difficulties occur in approximately one in 10 women and this ratio can increase with age (Chatoor and Emmnauel, 2009). Prolapse of any kind in the vaginal vault can be a distressing long-term condition,

affecting approximately 40% of women over 50 years of age, equating to 4.6 million women across the UK (Grimes and Lukacz, 2012, Hagen *et al.*, 2014, Statistics, 2016). However, emerging opinion on women's pelvic floor disorders identifies that this affects millions of women globally (Milsom and Gyhagen, 2019); for example, it is estimated that one in five women may require surgery for this problem by the age of 85 years (Milsom and Gyhagen, 2019). Although risk factors are known to be childbirth, multiparity, aging, and obesity, little is known about the histological causes (Grimes and Lukacz, 2012, De Landsheere *et al.*, 2013).

The impact of rectal emptying difficulty on women is primarily unknown and it is commonly a hidden problem (Eustice *et al.*, 2018). Women's health seeking behaviour with this problem can be low (Neels *et al.*, 2016). However, women may present to their general practitioner (GP) with related symptoms such as constipation. Constipation is associated with a defaecatory disorder and is four times more likely to be found in women than men (Noelting *et al.*, 2016). Women with rectocele causing their rectal emptying difficulty may resort to digitally positioning the anatomy to align the rectum for passing stools (commonly known as digitation or splinting) (Sultan *et al.*, 2016). A recent study identified that 56% of women with rectocele reported the need to use digitation to aid rectal emptying (Sung *et al.*, 2012).

Women's self-management options are poorly understood and as such, impact on their quality of life is lacking. Despite the scope of the problem and its effects on women's lives and health care, little attention has been paid to non-surgical

approaches (Douskos *et al.*, 2017). Non-surgical approaches can include both health care–initiated and self-initiated interventions.

Interventions that have been used for rectal emptying difficulty include self-initiated approaches, predominantly digitation or splinting, or health care–initiated approaches, such as suppositories, enemas, transanal irrigation, biofeedback (including pelvic floor muscle exercises), or electro-stimulation (Aigner *et al.*, 2011, Starr *et al.*, 2013, Cadeddu *et al.*, 2015). Differences between the two types depend on whether the individual is the lead initiator of the intervention. For instance, self-initiated implies that the individual can promote health with or without the support of a health care provider (Narasimhan *et al.*, 2019), whereas the health care initiated intervention, according to the World Health Organization, is ‘an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions’ (cited in Fortune *et al.* (2018) (World Health Organization, 2017). Whilst this emphasizes differences to a certain extent, it does not consider the acceptability of an intervention, which is a crucial consideration in terms of adherence and achieving optimum outcomes (Sekhon *et al.*, 2017). Interventions not incorporated in this review include oral laxative therapy, which is a familiar mainstay of primary care intervention for women who present with constipation (Bashir and Sizar, 2019) but has little effect on emptying the rectum where an anatomical defect is present (Podzemny *et al.*, 2015). Other common interventions that primary care can advise or offer are vaginal support pessaries, which commonly do not help improve rectal emptying (Bugge *et al.*, 2013). Consequently, such therapies are beyond the scope of this review. In pursuing a better understanding of what health care–initiated and self-initiated interventions

are used, a lens on the psychological impact of living with rectal emptying difficulty may emerge. The acceptability and usefulness of interventions are woven into how an individual manages anxiety or worry about their symptoms (Vrijens *et al.*, 2017). There is an increasing understanding of how bowel problems can affect the quality of life (McClurg *et al.*, 2012), mainly related to body image (Jelovsek and Barber, 2006) and activities of daily living (Jelovsek *et al.*, 2007). Problems with low self-esteem are also often identified during clinical consultations (Aujoulat *et al.*, 2008). The relationship between a woman and personal bowel function appears to be a largely private affair, and it takes courage for some to discuss these concerns with health care professionals (Tucker *et al.*, 2019). Fear and shame may lead women to find intuitive ways of managing their issues, such as digitation, without seeking a healthcare-initiated intervention. Digitation can be an uncomfortable process requiring good dexterity; it does not always work and can present additional problems with co-morbidities or increased age (Mustain, 2017).

A preliminary search of PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, and the JBI Evidence Synthesis was conducted and no current or in-progress scoping reviews or systematic reviews on the topic were identified. Strikingly, the literature was plentiful for diagnostic and surgical approaches (Douskos *et al.*, 2017, Mustain, 2017), providing a sense check that intermediate care, between diagnostics and surgery is lacking (Brown and Grimes, 2016, Giannini *et al.*, 2018). This lack of intermediate care has financial impacts on health care and the economy, but also increases the burden on quality of life (Racaniello *et al.*, 2015). This burden may be reduced by early identification of risk factors and easy access to nonsurgical, useful, and acceptable interventions. However, more needs to be known about the usefulness and acceptability of



interventions, which can translate into a meaningful non-surgical approach care pathway for rectal emptying difficulty due to ODS, secondary to rectocele.

Even though a range of interventions is available, this review was necessary to increase understanding of which interventions are used and helpful to women with rectal emptying difficulty and to inform gaps in the knowledge base.

### **3.4 Review question**

What health care–initiated and self-initiated interventions are used by women for the management of rectal emptying difficulty due to obstructive defaecation, secondary to rectocele?

### **3.5 Inclusion criteria**

#### **3.5.1 Participants**

This review considered studies that included adult women (over 18 years of age) experiencing difficulty with rectal emptying. Women with cognitive impairments, pregnant women, and those residing in care homes were excluded.

Interventions not incorporated in this review are oral laxative therapy, a familiar mainstay of primary care intervention for women who present with constipation (Aujoulat *et al.*, 2008) but has little effect on emptying the rectum where an anatomical defect is present (Tucker *et al.*, 2019). Another common intervention that primary care can advise or offer is vaginal support pessaries, which do not help improve rectal emptying (Mustain, 2017). Consequently, such therapies are beyond the scope of this review.

### **3.5.2 Concept**

The scoping review considered the concept of rectal emptying difficulties due to ODS secondary to rectocele, in adult females living in the community. The review examined what self-initiated and health care–initiated interventions are used for rectal emptying difficulties due to ODS. Self-initiated interventions included digitation or splinting. Health care–initiated interventions included suppositories, enemas, transanal irrigation, biofeedback, or electro-stimulation. It is acknowledged that some of these interventions could be both self-initiated or health care initiated and relied on the clinical experience of the author team to determine the difference.

### **3.5.3 Context**

This scoping review will consider studies that focus on adult women (over the age of 18 years) living in their own homes within the community.

### **3.5.4 Types of sources**

This scoping review considered all sources of data including experimental and quasi-experimental study designs, such as randomized controlled trials, nonrandomized controlled trials, before and after studies, and interrupted time-series studies, as well as observational type approaches. Qualitative studies included phenomenology, grounded theory, ethnography, qualitative description, action research, and feminist research. In addition, analytical observational studies including prospective and retrospective cohort studies, case-control studies, and analytical cross-sectional studies will be considered for inclusion. This review also considered descriptive observational study designs including case series, individual case reports, and descriptive cross-sectional studies for inclusion. Literature was searched from the initiation of the database to present but limited to English only.

## **3.6 Methods**

The scoping review was conducted following JBI methodology (Munn *et al.*, 2018) and reported using the PRISMA-ScR checklist (Tricco *et al.*, 2018, Peters *et al.*, 2015). Objectives, inclusion criteria, and methods for the scoping review were previously determined and detailed in a scoping review protocol (Eustice *et al.*, 2020).

### **3.6.1 Search strategy**

The search strategy aimed to locate both published and unpublished studies. An initial limited search of MEDLINE, Embase, CINAHL, and PsycINFO was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles, and the index terms used to describe the articles were used to develop a complete search strategy. The search strategy, including all identified keywords and index terms, was adapted for each included information source. Full search strategies for all databases accessed are provided in Appendix 1. For completeness, the databases were searched from the initiation of the database to 2019. The reference lists of all studies selected were screened for additional studies.

The databases searched included MEDLINE (Ovid), EMBASE (Elsevier), CINAHL (EBSCO), PsycINFO (APA), Emcare (Ovid), AMED (Ovid), Web of Science (Thomson Reuters), Scopus (Elsevier), PROSPERO (NIHR), International Clinical Trials Registry Platform Search Portal (WHO), UK Clinical Trials Gateway (NIHR), International Standard Randomised Controlled Trial Number Registry (ISRCTN), JBI Evidence Synthesis, Epistemonikos (Epistemonikos Foundation), Cochrane Library (Wiley). Unpublished evidence and grey literature sources included Open

Grey, ClinicalTrials.gov, MedNar, and ProQuest Dissertations and Theses (ProQuest).

### **3.6.2 Study selection**

Following the search, all identified citations were collated and uploaded into EndNote X7 (Clarivate Analytics, PA, USA) and duplicates (internal and external) were removed. The sources were then uploaded to RAYYAN systematic review software (Qatar Computing Research Institute, Doha, Qatar), facilitating the initial screening of abstracts and titles using a semi-automation process. Two independent reviewers screened the titles and abstracts for assessment against the inclusion criteria for the review. Potentially relevant studies were retrieved in total and their citation details were imported into the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia) (Munn *et al.*, 2019). The full text of selected citations was assessed in detail against the inclusion criteria by two independent reviewers. Full-text papers that did not meet the inclusion criteria were excluded and reasons for their exclusion are provided in Appendix 2. Any disagreements between the reviewers were resolved through discussion or with a third reviewer. A third reviewer was not required.

### **3.6.3 Data extraction**

Data were extracted from papers included in the scoping review by two independent reviewers using a data extraction tool developed for the review. The data extracted included specific details about the population, concept, context, study methods, and critical findings relevant to the review objective. The extraction table is provided in Appendix 3. Modifications were not required. Any disagreements that arose between the reviewers were resolved through

discussion. Contacting of authors of papers to request missing or additional data was needed. Authors of eleven abstracts were contacted to request access to the entire paper. Only one author replied to advise that the study did not go to complete publication (Aigner *et al.*, 2011).

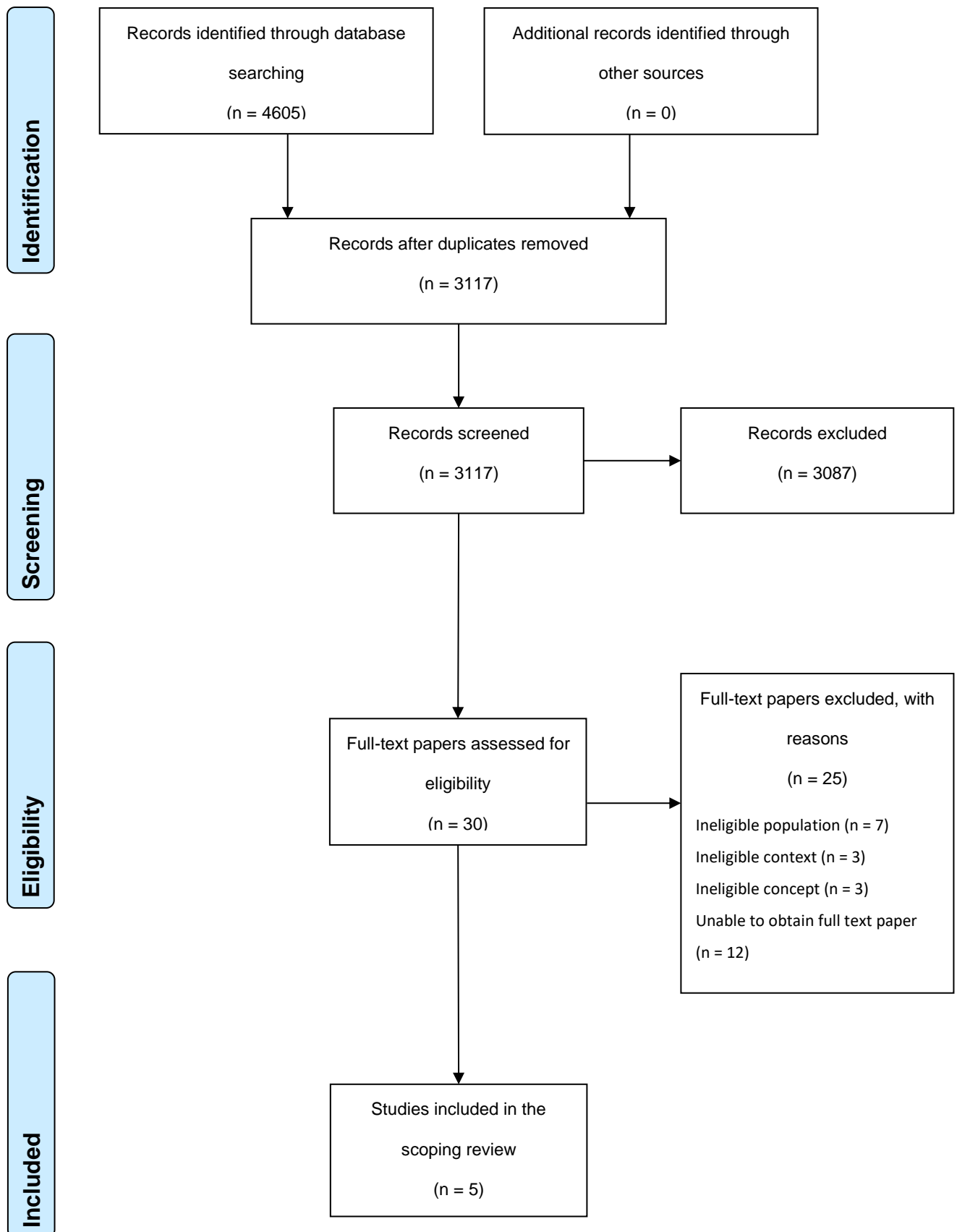
#### **3.6.4 Data analysis and presentation**

The extracted data are presented in diagrammatic or tabular form that aligns with the objective of this scoping review. A narrative summary accompanies the tabulated and/or charted results, describing how the results relate to the review's objective and question.

### **3.7 Results**

#### **3.7.1 Study inclusion**

From May to July 2019, 4605 records were identified through database searches. No additional documents were identified through other sources. One thousand, four hundred and eighty-eight duplicates were removed. Two assessors reviewed the titles and abstracts of the remaining 3117 records, and 3087 were excluded. Thirty papers were assessed for eligibility, and 25 papers were excluded. Seven papers were excluded because of the ineligible population, three papers because of inappropriate context (for example, not enough detail in the paper to address scoping review questions), and three papers due to concept (for example, no specific mention of rectal emptying difficulties). The remaining 12 papers were excluded because 11 were no full papers available. Eleven authors were contacted to retrieve the full-text paper, and the remaining study was reported on the clinical trials website only. Therefore, five full-text articles are included in this scoping review (PRISMA flow chart Figure 3.1) (Moher *et al.*, 2009) (Appendix 4).



**Figure 3.1: Search results, study selection, and inclusion process in the scoping review**

### **3.7.2 Characteristics of included studies**

Of the five studies included in this review, two were randomized clinical trials (Hagen *et al.*, 2014, Wen *et al.*, 2014), one was a prospective cohort design (Murad-Regadas *et al.*, 2012), one retrospective (Starr *et al.*, 2013) and one observational (Mimura *et al.*, 2000). The origin of the studies was the UK (Hagen *et al.*, 2014, Mimura *et al.*, 2000), Brazil (Murad-Regadas *et al.*, 2012), China (Wen *et al.*, 2014), and North America (Starr *et al.*, 2013). The oldest study dates to 2000 (Mimura *et al.*, 2000). A total of 1448 female participants were included in the studies. Amongst the studies, 700 female participants had obstructive defaecation. Detailed characteristics of the five included studies can be found in Appendix 4. Three studies reported outcomes for biofeedback therapy (Murad-Regadas *et al.*, 2012, Mimura *et al.*, 2000, Wen *et al.*, 2014), and two on pelvic floor rehabilitation (Starr *et al.*, 2013, Hagen *et al.*, 2014). The mode of delivery for all interventions in the studies was face-to-face and delivered in an outpatient setting or specialist unit. The intervention in four of the five studies was delivered by a specialist nurse, researcher, or physiotherapist. One study did not include detail of the type of provider (Murad-Regadas *et al.*, 2012).

### **3.7.3 Review findings**

#### **What health care–initiated and self-initiated interventions are used by women for the management of rectal emptying difficulty due to obstructive defaecation secondary to rectocele?**

The review considered what self-initiated and health care–initiated interventions are used for rectal emptying difficulties due to ODS. The five studies aligned with a range of healthcare-initiated interventions (Table 3.1). None of the studies

included a self-initiated approach. However, participants implemented interventions within the study protocols.

**Table 3.1: Health care interventions identified within included scoping review papers**

<b>Interventions</b>	<b>Study</b>
Biofeedback therapy	Mimura T <i>et al.</i> 2000 (Mimura <i>et al.</i> , 2000) Murad-Regadas SM <i>et al.</i> 2012 (Murad-Regadas <i>et al.</i> , 2012) Wen N-R <i>et al.</i> 2014 (Wen <i>et al.</i> , 2014)
Pelvic floor rehabilitation	Hagen S <i>et al.</i> 2014 (Hagen <i>et al.</i> , 2014) Starr JA <i>et al.</i> 2013 (Starr <i>et al.</i> , 2013)

### **3.7.3.1 Biofeedback Therapy**

Biofeedback therapy is ‘an instrument-based learning process that is based on ‘operant conditioning’ techniques’ (p.595) (Rao *et al.*, 2015), and the way it works is not fully understood. The three studies investigating biofeedback therapy used anorectal manometry as a core component, which involves active participation from patients to understand their bodily functions.

In an observational study by Mimura *et al.* (2000), biofeedback was offered to 32 participants who were bothered by rectal emptying difficulty. A biofeedback specialist nurse in an outpatient setting provided the intervention every two to three weeks, usually for four or five sessions. Using a structured questionnaire before, immediately after treatment, and at follow-up, the study identified three out of 25 patients experienced complete resolution of symptoms, followed by 22 patients noticing improvement in their symptoms. The proportion of patients who had to strain, experienced incomplete evacuation, used digital assistance or took



a laxative all reduced. None of these reductions, however, were statistically significant. Seven patients were lost at medium-term follow-up due to no contact.

In a prospective study, Murad-Regadas *et al.* (2012) describe the biofeedback therapy in most detail, which involves placing a catheter into the rectum and asking the participant to complete several manoeuvres while they watch the results of their effort on a screen (Murad-Regadas *et al.*, 2012). The study involved 103 participants who were provided with visual and verbal feedback as part of this intervention. In addition to the core component of biofeedback, fibre supplementation and increased fluid intake were included (Murad-Regadas *et al.*, 2012). The participants received clinical treatment for three months and were then assigned to one of three treatment groups. Group 1 included 34 participants exposed to clinical management only; in Group 2, 14 participants were exposed to the biofeedback, and 55 participants in Group 3 were progressed for surgery. Thirty-three per cent of Group 1 improved without biofeedback and in Group 2, 13.6% improved with additional biofeedback therapy.

In a randomised controlled trial, Wen *et al.*, (2014) compared the quality-of-life scores in 88 participants diagnosed with obstructive defaecation, allocating them to a biofeedback therapy or oral polyethylene glycol management group.

Participants were allocated by computerised randomisation to biofeedback therapy (n=44) or PEG (n=44) groups. The biofeedback therapy group were exposed to five weeks of 30 minutes training sessions within a general surgical department. Improvement of symptoms was achieved for 79.54% of patients in the biofeedback group.

### **3.7.3.2 Pelvic floor muscle rehabilitation**

Pelvic floor muscle rehabilitation includes the exercise of the muscle to maximise endurance, strength, and relaxation (Bo *et al.*, 2017a). Two studies focused on pelvic floor muscle exercises (Starr *et al.*, 2013, Hagen *et al.*, 2014). In their randomised controlled, multicentre study, Hagen *et al.* (2014) sought to determine the effectiveness of one-to-one individualised pelvic floor muscle training for reducing prolapse symptoms in 447 participants. Participants were randomised to the intervention group (n=225) or the control group (n=222), with a mean age of 56.8 years. Over 16 weeks, the intervention group was invited to five one-on-one consultations with a women's health physiotherapist for pelvic floor muscle training. The physiotherapist planned an individualised home exercise programme based on examination findings. The control group received a prolapse lifestyle advice leaflet and no pelvic floor muscle training (standard approach). At six and 12 months, women in the intervention group reported more improvement in prolapse symptoms than those in the control group. After six months of muscle exercises, the intervention group had a lower prevalence of each specific prolapse symptom and bladder, bowel, and sexual problems and a better quality of life.

Starr *et al.* (2013), in their retrospective study of 778 records, aimed to determine the efficacy of pelvic floor rehabilitation for women with pelvic floor dysfunction. The records were of participants referred for pelvic floor therapy for urinary, bowel, pelvic pain, and sexual symptoms over four years. The participants attended five therapy sessions (one every two weeks) provided by urogynaecology advanced practice nurses in an outpatient setting. Participants completed symptom questionnaires from their second to final visit. In each of the three categories of symptoms studied, there was an average symptom improvement of 80% (urinary

incontinence, defaecatory dysfunction, and pelvic pain). Defaecatory dysfunction (rectal emptying difficulty) showed significant improvement at the second and third sessions, but not after that.

### **3.8 Discussion**

This scoping review aimed to identify what health care initiated and self-initiated interventions are used by women to manage rectal emptying difficulty due to obstructive defaecation secondary to rectocele. Two health-care-initiated interventions have been identified. However, self-initiated interventions were not identified. Although the five studies reviewed do not add anything new, it does offer reassurance for clinical practice. Only one of the studies included detail on the quality of life (Hagen *et al.*, 2014, p.801) using the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF), which found women experienced improvement at six months of intervention, but not at 12 months. This questionnaire measures the frequency, severity, and impact of symptoms on quality of life. The variance in scores between six and 12 months is unexplained, perhaps influenced by shifting life experiences and perceptions and thus, symptoms have less priority.

Three of the five studies reviewed focused on biofeedback therapy, which suggested improvement in symptoms. Biofeedback therapy has been an integral intervention for many years and definitions of what it entails have been varied (Abrams, 2017). Usually implemented by therapists, it can be provided to children, women, and men for a range of pelvic floor disorders (Hite and Curran, 2020). Whilst the studies for biofeedback therapy involved using anorectal manometry as a core component, this is not always necessary. Regardless of

that, having access to biofeedback therapy may be out of reach for some women. Out of reach because primary care may not refer them onwards, or there is a lack of suitably trained health care professionals or women who accept their symptoms and do not seek help (Heidelbaugh *et al.*, 2021). Additional challenges for biofeedback therapy intervention are low adherence once women reach biofeedback therapy. For instance, Lepage *et al.* (2020) identified 68% of women at their Medical Centre in the United States did not complete their therapy. However, the majority did not have insurance. Therefore, finance was a key influencing factor. It is unknown about the adherence level in non-insurance-based health care systems. Despite biofeedback therapy resulting in positive outcomes, the availability of therapy, access and adherence are crucial factors for individual health gain (Narayanan and Bharucha, 2019).

Pelvic floor muscle rehabilitation has a wealth of evidence to support its position within the clinician or therapist's toolkit of options to offer women (Abrams, 2017). The results from the two studies are not unexpected given what is already known, especially concerning urinary incontinence (NICE, 2019). The studies reported improvement in prolapse symptoms and suggested that individualised instruction on pelvic floor muscle exercises yields more benefit than a standard approach (Hagen *et al.*, 2014, Starr *et al.*, 2013). Promisingly, the inclusion of women with obstructive defaecation within the study groups is encouraging and reinforces the opportunity to include pelvic floor muscle rehabilitation in caring for women with rectal emptying difficulty. Given the prevalence of pelvic floor disorders (Statistics, 2016) in women, equipping enough clinicians with knowledge and skill to deliver treatment is essential for timely access to care. Addressing this concern is a

randomised controlled trial (Waterfield *et al.*, 2021) investigating 240 women allocated to a primary care nurse, urogynecology specialist nurse for pelvic floor muscle exercises, or a control group (no exercises). The participants in the two intervention groups experienced similar symptom improvement. Therefore, it seems possible to train more clinicians for providing pelvic floor muscle therapy to their patients.

A significant limitation of this scoping review is the small number of published papers available for review, despite searching 15 databases. Unfortunately, 11 abstracts were not available to review despite contact with all the authors, thus restricting access to complete information and the opportunity to examine other interventions. Other interventions that did not reach included studies for this scoping review are trans-anal irrigation (Aigner *et al.*, 2011), sacral nerve stimulation (Proctor, 2016), digitation procedure (Haiying, 2014), and Botulinum A toxin (Botox®) therapy (Gurland, 2018). These interventions may be useful interventions for women with rectal emptying difficulty but remain unclear.

### **3.9 Conclusions**

This scoping review set out to identify what health care–initiated and self-initiated interventions are used by women to manage rectal emptying due to ODS, secondary to rectocele. Overall, two health-care-initiated interventions, biofeedback therapy, and pelvic floor muscle rehabilitation were identified. No self-initiated interventions were identified in this review. Whilst the interventions identified are used by and appear to help women with ODS. The findings are limited because other interventions exist but are not included in the review. Reassuringly these two interventions already feature within the toolkit of

conservative measures for clinicians. Although there is nothing new or innovative to add to current clinical delivery, this review offers a persuasive case for exploring further interventions, identifying a knowledge gap and innovations for women with rectal emptying difficulty due to ODS.

#### *Recommendations for research*

Future primary research is recommended to explore potential innovations for rectal emptying difficulty to add to the range of interventions that are already available and known to work. As per guidance, this scoping review did not assess the quality of the included studies. Therefore, the future methodological quality of studies for rectal emptying interventions will require assessment. If not of high quality, more high-quality studies will need to be conducted. Furthermore, future studies need to ensure consistent definitions and similar primary outcomes. Chapter 10 offers further recommendation.

#### *Recommendations for practice*

Building on existing care pathways to support women living with rectal emptying difficulty due to obstructive defaecation syndrome secondary to rectocele is recommended. The findings so far can reassure clinicians to offer the identified interventions as part of a pathway for women seen in their care with rectal emptying difficulty. It is possible to increase the quality of care by broadening the range of therapies available for women. Chapter 10 offers further recommendation.

### **3.10 Summary**

This chapter has concentrated on what interventions women use for the management of rectal emptying difficulty using scoping review methodology. Like the tapestry weaver, there is now a better view of the work's backbone, exposing some knowledge regarding interventions available and appreciating a knowledge gap. At this point, the positioning for the research journey (Chapter 1), against the backdrop of innovation and invention (Chapter 2), findings from the scoping review, along with the experiential learning and knowledge of the researcher (whilst also being the inventor and a clinician) are ideally situated to envisage a preliminary conceptual framework. Chapter 4 helps to explain how bowel mastery can be accomplished by examining the theories of social learning, self-efficacy, and coping behaviour; and determines how a preliminary conceptual framework offers a foundation for further discovery.

## Chapter 4 Theoretical position

### 4.1 Introduction

In this chapter the positioning of three theories will be the focus, to deepen understanding of how bowel mastery is accomplished. The relationship between social learning, self-efficacy, and coping behaviour is examined. Appreciation of how women currently cope with rectal emptying difficulty is facilitated by seeking explanation via these theories to help understand their lived experience. In turn, this drives the development of a preliminary conceptual framework, which offers a foundation for what has been discovered so far and what further discovery is needed along this research journey. Just as a weaver paves the way to design their tapestry, a conceptual framework can assist with providing clarity and direction for the study (Varpio *et al.*, 2020). The distinction between the conceptual framework and a theoretical framework has often been misunderstood and underused in research work (Leshem and Trafford, 2007). Deliberations by several authors across almost two decades (Varpio *et al.*, 2020, Maxwell, 2013, Green, 2014, Leshem and Trafford, 2007, Miles and Huberman, 1994) concur that the conceptual framework should visually validate why the research is essential, positioning the knowledge gap and what contribution the research makes. In other words, to furnish the thesis with coherence. This is in contrast to the theoretical framework, which differs by being a 'reflection of the work the researcher engages in' (p.990) (Varpio *et al.*, 2020). For this thesis, the conceptual framework is suitable. Given the intricacy of the problem being studied and its uncharted ground, the conceptual framework provides a visual approach to where the study has come from and where it is going and illustrates the gap in



knowledge. This chapter will explain how the concepts derived in the previous chapters have shaped the framework.

## **4.2 Theoretical positioning**

Understanding and unravelling thoughts about this research and how it aligns with a philosophical stance has required the researcher to take a step back from the daily grind of life to witness the art of living. The art of living is grounded in the Stoic tradition (Baltzly, 2018), which postulates that choice and control are within our grasp. A challenge of life recognises that we hold the gift to make choices and be in control. Many of us, including the patients seen in a clinical setting, especially the women with bowel dysfunction, struggle to take control, leading to frustration, despondency, and anger (Mussell *et al.*, 2008). A sense of balance between mind, body, and spirit is suggested to be necessary to take control and hence perceive a better quality of life, even if a disability exists (Cieza *et al.*, 2018). Thus, if we fully understand our power for having control and maximising our wellbeing, it could be argued that poor health might decline where choice and control are impeded. Merleau-Ponty's contribution that the body and mind are connected and perceiving that the two can be separated is not possible continues to be influential (Merleau-Ponty, 1945). The lived body is suggested to bond awareness and perception with the world (de Vignemont, 2018).

Physical symptoms and their influence on mental wellbeing are becoming more understood through societal recognition (Naylor *et al.*, 2016). Society and healthcare delivery have tended to require visible evidence of ill-health and only then fix the fixable. Therefore, non-visible symptoms e.g., anxiety, stress, pain, and other hidden ailments, yield less attention, if at all. Mental wellbeing and

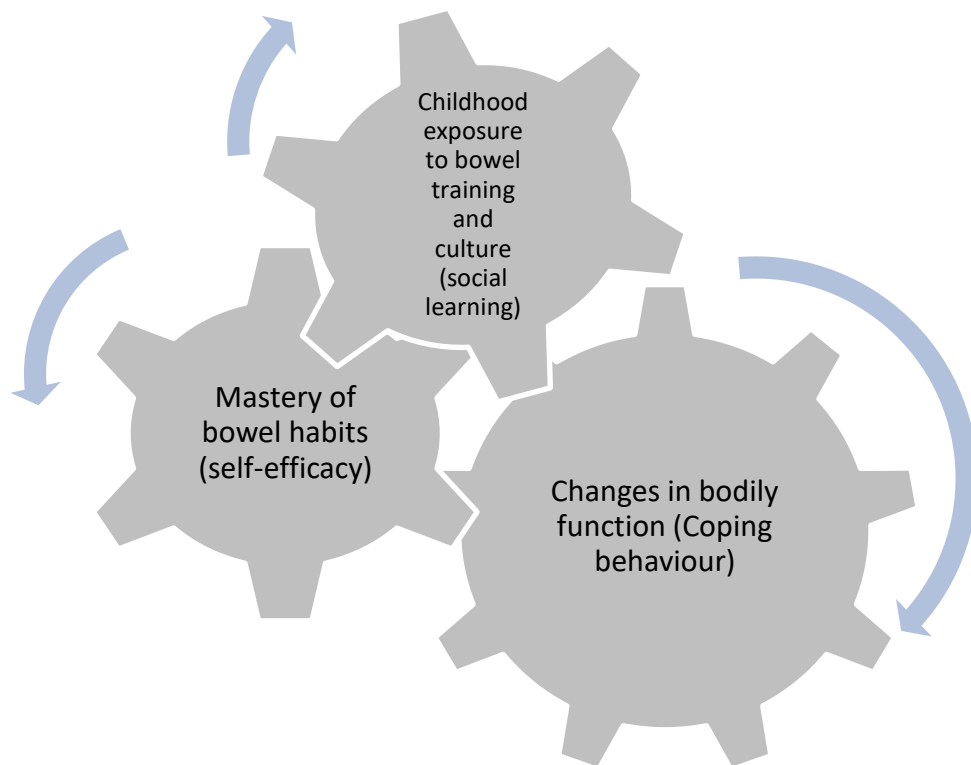
associated illness are having their profile raised, primarily due to celebrity influence (MIND, 2021). Furthermore, social media platforms can legitimise sharing of feelings that may be easier for some people to manage. Even so, there remains a raft of physical symptoms that remain not discussed or spoken of, especially those related to dealing with intimate bodily functions. Consider the common trait for many people to only defaecate in their toilet at home. It is an understandable, yet bewildering, human trait that prevents some people from emptying their rectums in public, school, or friends' toilets. The reasons for such behaviour can be complicated to articulate because it is so different from urinating in public, school, or friends' toilets, which is deemed acceptable for most. A rare insight into using lay language with bladder health and function identifies its divergence from medical terminology (Williams *et al.*, 2020). For example, the term 'urgency' is a recognised medical term (Fall *et al.*, 2002, p.168), which an individual may identify as 'having to dash to the toilet'. Thus, highlighting the challenges of a shared understanding of symptoms and what they represent for the individual to avoid misunderstandings, which may arise when the description of the problem is not easy for some people to articulate.

Reflecting further on bowel function psychology (Chapter 1), an additional complication woven into the fabric of our psyche is the phenomenon of disgust (Darwin, 1872) when talking about bodily functions. Disgust is an emotion felt by all, either moral or visceral (Jones, 2007). Moral disgust may elicit feelings in some people towards a homeless person. In contrast, visceral disgust might trigger a response of retching or gag to a smell, faeces, vomit, or such. Although this seems quite a simple concept, disgust can affect moral judgments and, thus,

behaviours and actions, a primal emotion woven throughout cultures (Curtis and Biran, 2001). On the contrary, disgust can be protective. Protecting the body from repellent food, so retching is the body's way of expelling a toxin. Current marketing portrays products for feminine hygiene as fresh, clean, or discreet (Jenkins *et al.*, 2018), appealing to the need for sanitisation and cloaking the reality of human messiness. Of interest is the point at which one's bodily waste becomes disgusting. Whilst within the body, it does not elicit feelings of disgust, once it becomes external and can be seen outside the body, it may manifest this emotion of disgust (Rozin and Fallon, 1987).

### **4.3 Chronology of bowel mastery**

Selecting an analytical lens for the research required much thought and probing of the literature (Dipper *et al.*, 2021). Unsurprisingly, this was not straightforward given the uncharted territory of the research. The research draws upon three theoretical positions that stretch across a chronology of bowel mastery (Figure 4.1).



**Figure 4.1: Bowel mastery linked to theory**

Figure 4.1 illustrates interactions or cogs of the wheels driving a lived experience from childhood into adulthood. Selecting only one theoretical position does not do justice to the situations' complexity, and thus multiple lenses were required. The most closely aligned theories are social learning theory, self-efficacy, and coping behaviour, which intervene and are possibly symbiotic. Children exposed to, and taught toilet training behaviour draw on social learning theory (Bandura, 1977b). Albert Bandura was an American psychologist who built on previous thinking (Iversen, 1992) that children can learn through imitating and rehearsing behaviours from others, especially their parents or carers. Active learning in this context requires specific elements, such as cognition, observation, environment, and reinforcement. Positive behaviour towards toileting requires role models to

help reduce the risk of a negative attitude with faecal matter. How early experience of toileting influences individuals to seek or not seek help for a bowel problem in adulthood is not evident. Although social learning theory is applicable into adulthood, it is uncommon for healthcare professionals to ask about childhood experiences in clinical settings. According to Hughes' *et al.* (2017) systematic review, multiple adverse child events could influence health conditions throughout life. Although toilet training experience mainly falls outside the seriousness of adverse child events, the potential to enhance clinical enquiry deserves further attention.

The impact on self-efficacy may shape the ability to cope with healthcare issues. If low self-efficacy exists, this may influence the ability to manage well. With a stronger perceived self-efficacy, the increased likelihood of approaching the problem with positive behaviour is possible. So determined by self-efficacy, how well a person can cope with an obstacle, trauma, or adverse experiences is important (Holloway and Watson, 2002).

#### **4.3.1 Social learning theory**

The chronology begins with children being exposed to and taught toileting training behaviours (Bandura, 1977b). Social learning theory can also be traced back to work by Akers (2013) in the field of criminal or deviant behaviour. Bandura applies the theory to non-criminal or conforming behaviours, and he proposes that children are exposed to four processes: attention, retention, reproduction, and motivation, which facilitate behaviour. In the context of toilet training, the child copies a sibling or parent with going to the toilet. Thus, the child's attention is seized. Next, the child needs to remember or retain the information, followed by

replicating or reproducing the behaviour. Finally, the child needs the will or motivation to continue the behaviour. Woven through this may be rewards and punishments, depending on parental styles. Although this theory illustrates a sense of simplicity and appears to be centred on observation, cognition such as thoughts and feelings can also shape the experience. Mainly, social learning theory helps to give insight into how children can develop the social skill for toileting. However, the complexity of child development can extend beyond the reaches of social learning theory. One of its criticisms is the reliance on others (family and friends) to adapt a behaviour (Wortley *et al.*, 2008).

As in what the child observes, positive role models for toileting training may help reduce the risk of a negative attitude towards faecal matter (van Nunen *et al.*, 2015). Although not fully understood, this early experience might influence how people seek help for a bowel problem in adulthood. The early experience draws on toilet training methods implemented by parents, who are considered integral to helping their children master bodily function, which is a complex process, usually by the age of four or five years. Methods of training the child to use the toilet have varied over the last century, predominantly fostering two approaches, grounded in the early works of paediatricians and psychologists. One approach is child-led (relying on the readiness of physiological and behavioural factors) (Brazelton, 1962) and the other is parent-led (Azrin and Foxx, 1974). The parent-led approach relies on when the parent believes it to be the right time to begin toilet training, which can be influenced by their own experience, social factors, and culture. Much has been written about toilet training, especially in the 1970s (Azrin and Foxx, 1974). However, there is minimal evidence to indicate what method works best

(Vermandel *et al.*, 2008). Whatever approach is taken, the parent is crucial in toilet training for their child. Of course, most of this is postulated on the child not having any additional needs (for example, autism, language and speech problems, Down syndrome, cerebral palsy, and attention deficit disorder) (Greenspan *et al.*, 1998). Children with an additional need should still be exposed to toilet training opportunities, although it is recognised that the process can take longer (Richardson and Rogers, 2017).

Parents whose children have toileting problems may not access help or advice with or without an additional need. In a cross-sectional study within a semi-rural part of Nigeria, 200 caregivers who attended a paediatric outpatient clinic were recruited and invited to complete a questionnaire. Of these, 31% reported their children as having a bladder or bowel problem, but only 24% of them sought help. Fifty-two percent of the caregivers were men and ethnicity or educational attainment were not noted to be factors (Lawal *et al.*, 2019). In contrast, a European study recruiting 2000 parents was also invited to complete a questionnaire, suggesting that mothers with higher educational attainment were more likely to toilet train their children before entering nursery or school (van Nunen *et al.*, 2015). Cultural differences of these cross-sectional studies mean that the findings may not be generalisable to the population of the United Kingdom. They thus will influence interpretation (Uzun, 2020) and needs cautionary reading.

Negative consequences of delayed toilet training can include hygiene problems in the nursery or school, and unpleasantness for the child. Whether or not a delay in

toilet training can harm bladder and bowel function during childhood is not fully understood (Wu, 2010). Netto *et al.* (2021) investigated associated factors with delay in toilet training by administering questionnaires to 372 parents in South America. Most parents used a child-led approach and the children (both boys and girls) achieved toilet training by an average of 2.5 years. Association with bladder or bowel dysfunction was not identified despite age at toilet training. However, most children were trained before 36 months (n=291) compared to 73 children older than 36 months. Previous to this study, a systematic review that meta-analysed ten papers with 24,121 participants (aged between 5 and 17), found that earlier toilet training can reduce the onset of lower urinary tract dysfunction (Li *et al.*, 2020). However, very little has been written about the impact of toileting training on bowel dysfunction. Taubman *et al.* (2003) offer some insight into the children who stool withhold, hide to defaecate or display toilet refusal and the associated challenges, such as constipation. They found that children who hide their stool were exposed to toilet training a few months later than non-hiding children. It is unknown what impact delayed toilet training has on behaviour in adulthood (Uzun, 2020).

#### **4.3.2 Self-efficacy**

Following on in the chronology of bowel mastery is self-efficacy. Bandura extends his work on social learning theory and postulates the position of self-efficacy as an important construct in understanding human behaviour (Bandura, 1977b).

Although self-efficacy is commonly discussed in the social psychology literature, it is not commonplace in everyday language. Thus, it can be challenging to explain what it is or is not. Self-efficacy is suggested to be a belief in one's capability to complete a task or action (Williams and Rhodes, 2016). Closely related, but easily



confused, is self-esteem, commonly used in everyday language, the perception of negativity or positivity towards oneself (Cast and Burke, 2002). In the context of this research, self-efficacy theory has a closer match when investigating lived experience. Bandura (1977a) believes that if low self-efficacy exists, this may accompany an inability to cope well. Hence implying that a strongly perceived self-efficacy may lead to an increased likelihood of approaching a problem with positive behaviour. However, self-efficacy does not stand alone as a concept.

According to some authors, self-efficacy is interwoven with 'perceived behavioural control', which is the ease or difficulty of performing a behaviour (Ajzen, 2002, Yang *et al.*, 2020). Their analysis of perceived behavioural control is applied as an overarching concept, with self-efficacy and controllability as subordinate concepts. Nevertheless, these concepts are critical to understanding how a person uses internal and external factors influencing their behaviour. Interpreting this into the real world suggests that perceived behavioural control is the ability to perform something, underpinned by the ease or difficulty of performing (self-efficacy) and the belief in one's ability to perform (controllability) (Rodgers *et al.*, 2008). However, this proposition can be refuted when introducing the concept of perceived difficulty (Trafimow *et al.*, 2002). These authors suggest that perceived control and perceived difficulty are two separate paradigms. That said, whatever the paradigm, self-efficacy can be viewed as integral to both. A further understanding is offered by Povey *et al.* (2000), who suggest that self-efficacy and perceived control have different influences on healthy eating in their questionnaire study of 287 members of the general public. They identified that self-efficacy was influenced by knowledge and motivation, and superior to perceived control in

changing behaviour. Furthermore, a study by Keefer *et al.* (2010) explored the role of self-efficacy in determining treatment outcomes in a convenience sample of 122 people with inflammatory bowel disease using validated questionnaires. Their findings suggest that, despite the range of symptoms experienced, the perception of self-efficacy was a determining factor in achieving treatment outcomes. These studies reflect a common element of self-talk in that 'I can do....' and thus could be considered a proxy for motivation (Williams and Rhodes, 2016). Critiques of self-efficacy theory have populated the literature over the years and there continues to be an exploration of the dynamics of self-efficacy (Yeo and Neal, 2013). That is not to say that the concept of self-efficacy is being sabotaged. Merely new thinking is attempting to expand its understanding. Therefore, self-efficacy remains important and vital to the chronology of bowel mastery.

#### **4.3.3 Coping behaviour**

The final cog in the chronology wheel for bowel mastery is coping behaviour. Coping behaviour has been richly emphasised within the work of Lazarus and his colleagues (Lazarus, 1993, Lazarus and Folkman, 1987). Their pioneering work suggests that coping behaviour is determined by self-efficacy. In other words, how well a person can cope with an obstacle, trauma, or adverse experience is predicated by their confidence. There have been minimal claims to refute this theory, and although the work of Krohne (2002) has offered reinterpretation, the views of Lazarus (1993) remain prominent. Coping strategies have been studied over several decades (Holahan and Moos, 1986, Trew, 2011). However, a recent interpretation of coping has emerged which offers a supplementary intuitive perspective and may resonate more with contemporary life, as portrayed by Stallman (2020). Stallman's work draws on Skinner *et al.* (2003), their seven-step

criteria for a functional approach to reducing distress. Skinner *et al.* (2003) offer a continuum of actions consisting of healthy environments, responsive parenting, a sense of belonging, healthy behaviours, coping, resilience, and treatment of illness. Stallman (2020) takes this work further by conceptualising healthy and unhealthy behaviours, which provides accessible clarification. For instance, her categories of self-soothing, activities, social and professional support describe healthy and unhealthy behaviours within each category. Therefore, integration with traditional healthcare models is more likely to be accepted and utilised. Uncovering women's hidden, unspoken stories might also benefit from a patient-focused theoretical framework focusing on stress and coping. Furthermore, theories that compliment the implementation of evidence into practice are of particular interest. Chosen theories in this research (social learning, self-efficacy, and coping behaviour) required likeness to the project aspirations and align intuitively to the characteristics of the women being studied. Characteristics include the concept of stress and coping. Women with bowel problems must find ways to cope, searching for solutions (or not) to make everyday life bearable and comfortable. The concept of coping is something known to each of us in various contexts. These contexts can comprise the interplay of emotions, self-awareness, and strength of character and are likely to influence how each person interacts with the stressor. This interplay has been illuminated within two frameworks that promise more profound understanding (Lazarus and Folkman, 1987, Roth and Cohen, 1986).

The first of these frameworks centres on dealing with stress, which tends to avoid or approach a situation (Roth and Cohen, 1986). In this model, a stressor is direct

or indirect for the individual, challenging norms, and comfort. Therefore, personal resilience may influence the natural state of avoiding the stressor or approaching it. Applying this to experiencing a rectocele that fails to empty stool effectively, causing discomfort, the woman may be forced to consider ways to deal with it. Dealing with it may include accessing healthcare (e.g., General Practitioner) to seek information and understanding; and implementing digitation. Both ways of dealing with the problem suggest an approaching style, according to Roth and Cohen (1986). Whereas trying to ignore it, using indirect strategies (laxatives, more toileting visits) implies an avoidance style (Bauer *et al.*, 2016). Roth and Cohen (1986) advise that there are consequences to each approach. Both can offer benefits but with risks. However, the model is not a precise solution for understanding it all. Women may shift between the two states depending on situational factors, such as social and intimate relationships.

The second, closely linked framework, is of cognitive appraisal and coping (Lazarus and Folkman, 1987). In this instance, the individual interprets the stressor (primary appraisal) and determines its relevance (secondary appraisal). Stress occurs when there is a threat or challenge, and resources are insufficient to manage it. Coping in this situation is suggested to be emotion or problem-focused to help overcome the stressor. Reappraisal occurs at different points in time to pace and learn.

Coping is a necessary internal process that all humans experience, across a continuum of minor annoyances in everyday life to catastrophic events (Hoyt *et al.*, 2016). Within the literature, authors have deconstructed and dissected the

concept of coping with varying perceptions, attempting to make sense of this most complex of domains (Stallman, 2020). Coping strategies have been studied in multiple health care conditions, such as menopause (Simpson, 2016) and coronary heart disease (Endler, 2001). During 2020, coping strategies were brought into sharp focus because of the COVID-19 global pandemic (Park *et al.*, 2021). Despite an unfortunate and devastating experience for human life, the fresh emergence of mental wellbeing may be an unintended benefit.

The convergence of the three theories (social learning, self-efficacy, and coping behaviour) helps to guide attention to the broader story of women with rectal emptying difficulty. As Powner (2014) eloquently suggests 'Theories are simplifications of reality' (p.22). The theories have a positive relationship and may help explain the meaning, nature, and challenges facing women and device implementation success. Applying a lens across three theories could be likened to theory triangulation because each theory offers a different perspective along a timeline from child to adulthood. Several approaches to triangulation exist (Rugg, 2010), including data, methods, and investigator. Origins of triangulation reached back to mathematics and were evolved into sociological methodology in the 1970s, predominantly by the work of Denzin (2012). Application of theory triangulation has been seen within the interpretation of data (Turner and Turner, 2009). However, in the context of this research challenges for women with rectal emptying difficulty are multi-dimensional. Thus, one theory does not appear to do justice, so a combined relationship fits better. However, the ongoing journey beyond this research will reveal complexities and implementation into clinical

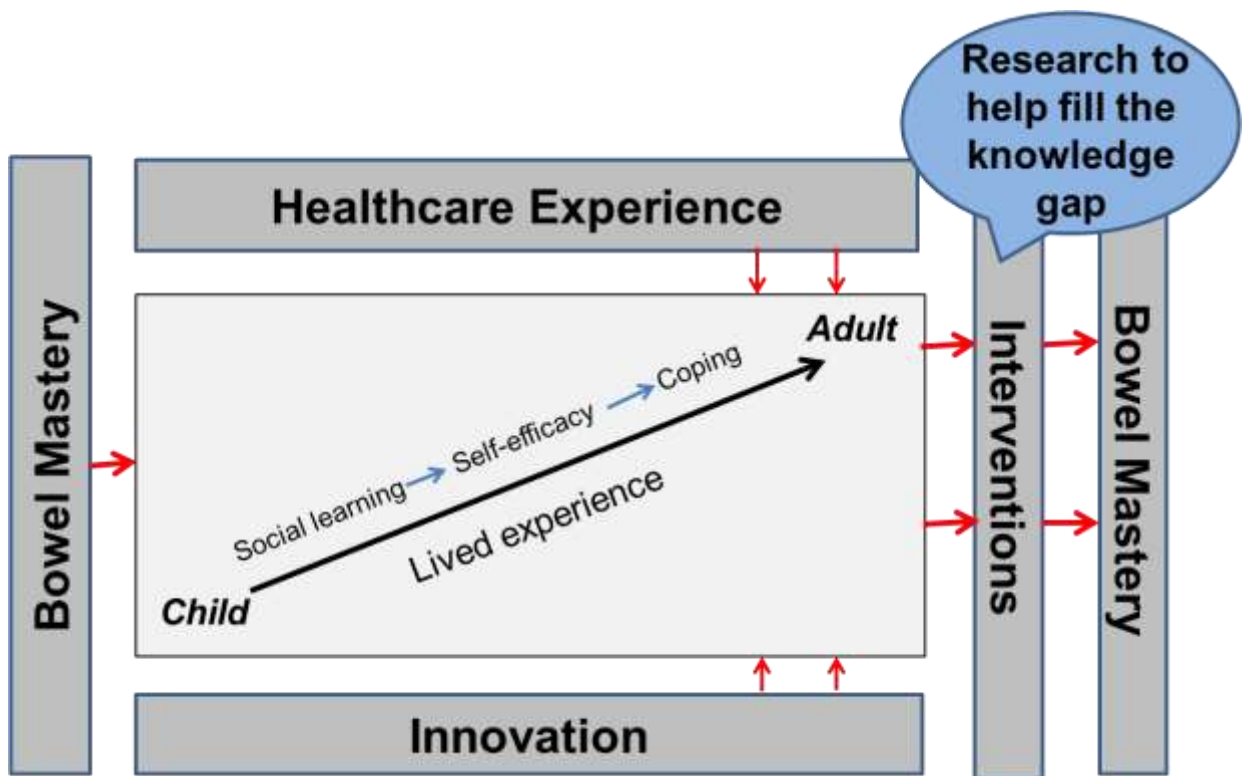
practice that truly makes a difference. In addition, the theoretical position has aided the development of a preliminary conceptual framework.

#### **4.4 Development of a Preliminary Conceptual Framework**

As previously detailed in Chapters 1, 2, and 3, the research focuses its inquiry on using a patient-centred device to help women who have rectal emptying difficulty due to obstructive defaecation secondary to rectocele, manage their symptoms more effectively and satisfactorily than their usual methods. Additionally, the research aims to improve understanding of the lived experience for women who face this problem. Setting the development of the framework at this juncture in the thesis draws on the theoretical position for the study, the scoping review, and the experiential learning and knowledge of the researcher (who is also the inventor and a clinician).

Beginning to build a conceptual framework can be challenging and daunting. Whilst there is a developing opinion on how to do this (Green, 2014, Maxwell, 2013, Miles and Huberman, 1994), the researcher is still required to muster depth of thinking and decision making on what is essential for their work. Considered an indispensable feature in a thesis (Adom *et al.*, 2018), the conceptual framework aims to lift the quality of research and provide a window into constructs to be studied. For this study, a concept map was produced (Appendix 5) which provided a picture to highlight the range of factors that women can encounter. From there, a framework emerged and was developed (Figure 4.2), which is a visual capture of the woman's linear journey. As previously explored, role modelling for toileting training in childhood, an individual's belief system in looking after themselves, and how coping with adverse situations help elaborate the

complexity of bowel function. Thus, revealing the complexity of what can seem a simple fact of human life.



**Figure 4.2: Bowel Mastery Conceptual Framework**

#### **4.5 Central concepts of the conceptual framework**

The central concepts are both intrinsic and extrinsic. Intrinsically, the journey involves the lived experience from childhood to adulthood, in the context of mastering bowel health, drawing on social learning and self-efficacy theories (Bandura, 1977b, Bandura, 1977a). Furthermore, it also involves how women cope with rectal emptying difficulty in adult life, and how this is difficult to untangle from their previous life experiences and thus can influence the coping strategies they adopt (Lazarus, 1993). Extrinsically, wrapping around and supporting these concepts are the interventions that women may access or be signposted to via the

contribution of healthcare experience. However, this contribution can motivate innovative practice, striving to do better for those in our care. Achievement of bowel mastery is a lifelong skill, therefore the 'bookends' of the conceptual framework (Figure 4.2) reflect this.

Achieving bowel mastery exemplifies the interrelatedness of the influencing factors. As Bordage (2009) advises, the conceptual framework aims to enlighten and understand a complex problem. However, the subjectivity and intuitiveness of the conceptual framework lay it open to misinterpretation. Whilst the conceptual framework can be a challenge, Durham *et al.* (2015) remind doctoral researchers they should endeavour to address this. Thus, identifying the research necessary to help fill the knowledge gap, which sits within the intervention element of the framework, is integral to setting the scene.

#### **4.6 Filling the Knowledge Gap**

Filling the knowledge gap is two-fold in its nature. Firstly, interventions available for women with rectal emptying difficulty are limited, as seen in Chapter 3, which has explored the existing evidence via a scoping review. The scoping review findings identified that two interventions were available, these being healthcare initiated. No self-initiated interventions were identified, highlighting a gap in clinical practice and the evidence base. Secondly, the limitations of available interventions within healthcare provides an opportunity to offer an alternative option, underpinned by the woman's life experience story to advance understanding. Achieving improved bowel mastery can be enhanced by filling this gap.



## **4.7 Summary**

The position of the three theories (social learning, self-efficacy, and coping behaviour) has guided attention to the broader story of women with rectal emptying difficulty. The choice of theories offered likeness to the project aspirations and aligned intuitively to the characteristics of the women being studied. The preliminary conceptual framework was further shaped by the scoping review findings, and the experiential learning and knowledge of the researcher (who is also the inventor and a clinician). Developing the conceptual framework provides an illustrative, woven representation of the concepts that have emerged from the previous chapters, primarily from the theoretical positioning, scoping review, and research experience. Moreover, it facilitates clarity on why this research is essential; and what contributions it will make to the lives of women who experience rectal emptying difficulty. Chapter 5 details the design and methods of the research.

## Chapter 5 Design and Methods

### 5.1 Introduction

The ontological and epistemological foundations of the research design is explained in this chapter. Along with the rationale for choosing mixed methods research (MMR), adopting an explanatory sequential design to address the problem, and how the three phases (exploratory, phases 1 and 2) were conducted. This study is designed to address the two research questions:

1. Does the patient-centred device help women who have rectocele, manage obstructive defaecation, secondary to rectocele more effectively and satisfactorily than their usual methods?
2. What is the lived experience like for women who experience difficulty emptying their rectum because of obstructive defaecation secondary to rectocele?

Like this study, the loom to hold the tapestry while crafting represents the method, holding the weave together, providing stability and confidence in the finished product. The study focuses on two components, firstly using a patient-centred device compared to women's usual care in managing the rectal emptying difficulty. Secondly how these women (same sample) live with the experience of rectal emptying difficulty. The lived experience of women suffering from bowel problems, particularly with difficulty emptying their rectum and needing digitation is misunderstood, covert, and needs to be examined.

Deciding on the design for systematically investigating the impact of a patient-centred device was complex, especially when there is little or no underpinning evidence or established position within clinical care with which to guide this

inquiry. Fortunately, the MRC guidance helped shape discussions and decision-making (Craig *et al.*, 2013). Driving the research was the influence of the women who had self-purchased the patient-centred device. Many had posted comments on social media, which were unsolicited and revealed the difficulty in managing obstructive defaecation, such as '*how on earth do you get poo out of a rectocele without pushing it out manually. It just doesn't come out*' (Stress No More, 2017). Therefore, social media was an influencing factor for the rationale to investigate rectal emptying difficulty due to obstructive defaecation secondary to rectocele, and its impact on women (Stress No More, 2016); and supported the rationale for undertaking Phases 1 and 2.

## **5.2 Ontology and epistemology**

### **5.2.1 Ontology**

Ontology is the theory of objects and their relationships (Marsh and Furlong, 2002). The ontological assumption underpinning this research is that freedom from bowel dysfunction is an expectation of every human being. Whilst there is the suggestion of an objective position, the lived experience of body function/dysfunction requires further understanding. The field of biology explains that faecal matter is stored and evacuated from the rectum via a complex array of physical and physiological factors (Liao *et al.*, 2009). The expectation of mastering these bodily functions can partially be explained by the theories (social learning theory, self-efficacy, and coping) chosen to provide a perspective on this work (Bandura, 1977b, Bandura, 1977a, Lazarus, 1993). Furthermore, the application of empowering physical health draws on the self-efficacy element of

the theory (Rappaport, 1984). The notion that loss of bodily control is an assault on feelings of worth and control supports this claim (Aujoulat *et al.*, 2008).

The research design has been developed from a combination of published literature, a scoping review, clinical knowledge, and experience. However, there is a body of knowledge missing in rectal emptying difficulty, which is how women live with this problem. Thus, it is necessary to understand the perspectives of women presenting with this condition and then untangle the interwoven physical, emotional, and social elements that permeate the different clinical, investigator, and inventor roles within this research. By untangling the physical, emotional, and social elements faced by women, there is an opportunity to deepen understanding (Bandura, 1977b, Bandura, 1977a, Holahan and Moos, 1986, Kitson *et al.*, 2008, Lazarus, 1993, Lazarus and Folkman, 1987, Roth and Cohen, 1986, Trew, 2011).

### **5.2.2 Epistemology**

Epistemology is centred on the theory of knowledge (Marsh and Furlong, 2002), focusing on justifying position and belief. The epistemological position for the research is that bowel dysfunction in adult females restricts freedom. The concept of freedom has been associated with responsibility; and subsequently better health (Bunker *et al.*, 1996). Most people want to be happy, free, and healthy as described by Hornsey *et al.* (2018) in their study of nine regions across the world seeking out cultural differences using questionnaires as a data collection method. The study findings suggest that people seek perfection in different ways that may influence how free they wish to be. An alternative view is that freedom is by chance alone (Frankfurt, 2018). It could be argued that defining freedom is complex. For instance, freedom of choice and free will, invite a different context. Even though Stoic tradition talks of freedom, each proponent of their philosophy

offered a different perspective, although eventually concluded that freedom is the self who acts, and the resultant behaviour is the outcome of an act of agreement (Bobzien, 1997).

Drawing together the view that freedom from bowel dysfunction is the expectation of every human being and that living with a bowel dysfunction in adult human females restricts freedom, compels a need to focus attention on this issue. This research aimed to seek to understand better what this means for women and reveal new understanding and insight to apply it more widely. Ontologically, an objective position that sets the scene for investigating the meaning of bowel dysfunction in the female population. This scene-setting provides both inductive and deductive processes (Crotty, 1998). Inductive discovery (or interpretivism) assists with discovering themes from the lived experiences of women by focusing on meanings. In contrast, deductive proof (or post-positivism) will assist with investigating the effect of a patient-centred device to help defaecation by concentrating on facts (Ekins *et al.*, 2017). Integration of these processes lends itself to a mixed-method design.

### **5.3 Implementation of evidence into practice**

The absence of clinical evidence on how best to help women with difficulty emptying their rectum was instrumental in starting this research journey. Whilst pump-priming funding was available to kick-start the innovation, the schemes did not include scientific exploration through research methods. The NHS process stops short of this critical stage for testing the efficacy of innovations. Possible reasons for this may be risk aversion, change resistance, and a negligible entrepreneurship culture (Castle-Clarke *et al.*, 2017). Seeking ways to overcome

these barriers focused on clinical leadership because the research would not have happened without this. Without the skill of persuasion, this research may not have continued because the topic was considered niche and low profile. Therefore innovation-focused clinical leadership was vital otherwise, the nursing contribution to research may remain in the shadows (Bagheri and Akbari, 2018).

Evidence-based practice identifies that the evidence comes from many different sources; best research evidence, clinical expertise, and patient preferences and wants (Sackett, 1997). The recognition of the need for more evidence emerged from the researcher's own clinical practice experience, which identified that women intuitively approached rectal emptying difficulty by using digitation, in other words, their fingers to empty the rectum. Additionally, those women who chose to buy the device of their own volition helped shape this research further; their input was valuable and essential. The impromptu product feedback provided by these women highlighted the need to investigate more fully the use of the device, but it also identified an opportunity to shine a unique spotlight on how they cope with such a problem. Whilst clinical knowledge and experience had identified a gap in the healthcare options available for women and an inconsistent approach in care. It was also vital to discover the underpinning theory (Chapter 4).

Starting the innovation journey involved capturing of the initial idea for the patient-centred device, modelling a prototype, and adoption to the marketplace, but these were primarily initiated from a practice perspective. The shift of perspective to that of a researcher occurred with introducing a Public and Patient Involvement (PPI) group. The PPI group provided a coherent expression of suffering and

feelings of isolation, revealing many women's the hidden and unspoken voices, hence shaping the research design. Furthermore, creating a preliminary conceptual framework depicts the journey and aids the development of an implementation framework that fosters elements necessary for improved benefit and meaningfulness to healthcare.

Given the range of components in such a fascinating subject, this research is only just beginning to lift a lid on a hidden world on women's experiences, brought about by finding a solution to a common problem. The solution was the use of a patient-centred device. However, the research associated with this device use required the following questions to be answered:

1. Does the device help women who have rectocele, manage obstructive defaecation more effectively and satisfactorily than their usual methods?
2. What is the lived experience like for women who experience difficulty emptying their rectum because of obstructive defaecation secondary to rectocele?

#### **5.4 Mixed methods and Pragmatism**

Mixed methods research (MMR) has been subject to scrutiny and varied opinion (Tashakkori *et al.*, 2020). MMR is no longer considered as a newcomer to the traditions of the singular qualitative or quantitative approaches. Although many eminent authors have tackled and described the components of MMR (Teddlie and Tashakkori, 2003, Cresswell and Plano Clarke, 2018, Maxwell, 2016, Flick, 2017), they have also challenged MMR's position in traditional research design. In particular, Maxwell (2016) and Flick (2017) refer to their frustration with the lack of attention and understanding regarding the origins of MMR; even though not

labelled as MMR, early interpretations cast insight into using this approach.

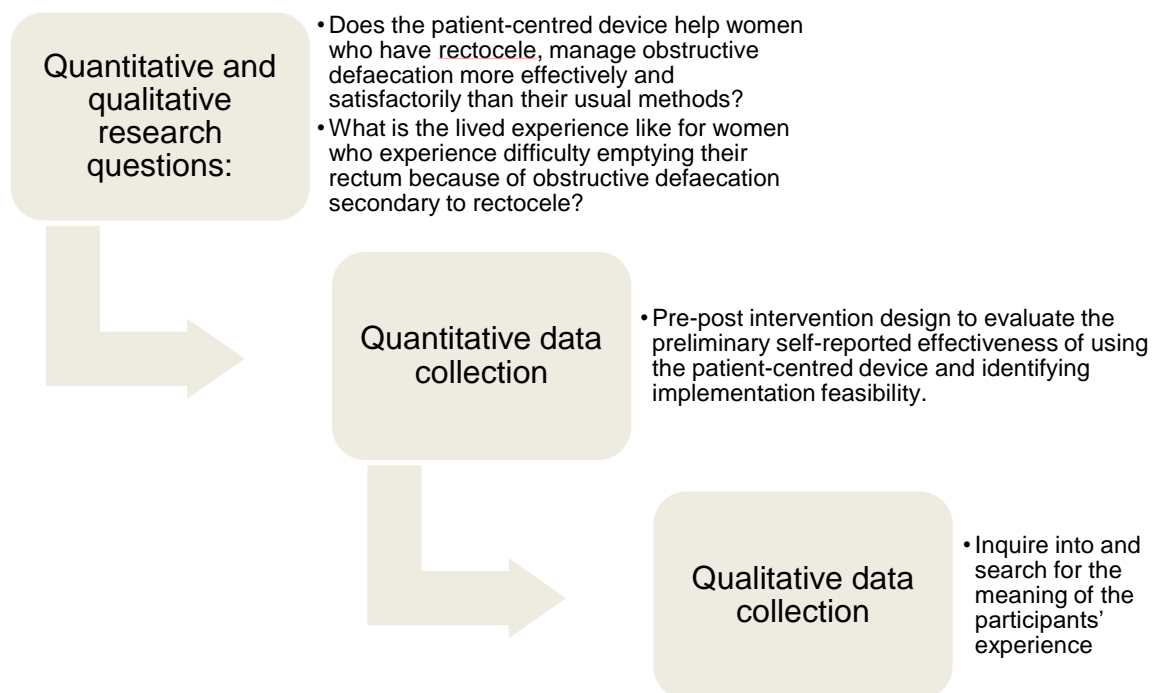
Maxwell (2016) highlighted the work of Galileo as a case in point, who many years ago applied observations and measurement to make sense of astronomy in the pursuit of knowledge.

The traditions of singular worldviews from a quantitative or qualitative position have been long advocated but justly challenged (Tashakkori *et al.*, 2020). Shifting sands of human nature and its intricacy require a more balanced interpretation of the real world (Baškarada and Koronios, 2018). O’Cathain *et al.*’s (2008) work on investigating the quality of reported MMR research in healthcare services provides the researcher with a tool to measure the robustness of their work. O’Cathain *et al.* (2008) concluded that, although attention was paid to the individual components of mixed-methods, minimal attention was paid to the mixed-method design. Other tools to measure robustness have included Cresswell and Plano Clarke (2017) and Pluye *et al.* (2009). All authors emphasise the necessity to ensure the quality of both reporting and reviewing MMR. Given MMR’s quest to secure its place in the modern world, researchers must aim for transparent and justified study design. Facilitating transparency is guided by a pragmatic approach.

The philosophy underpinning this research is that of pragmatism. Pragmatism was initially considered by John Dewey, the American philosopher, whose emphasis was on what works to answer the research questions of human experience (Boydston, 1969). More recently, an eloquent attempt has been made to ground pragmatism into philosophical potency (Morgan, 2014). Nothing is perfect, as the philosopher Epictetus suggested (Long and Spalding, 1904) and so



to do what needs to be done to delve into uncharted territory is necessary. Therefore, this research draws together the observable (post-positivist) and the subjective (interpretivism), providing a richer understanding than either alone (Greene, 2006). In the world of the tapestry weaver, the wefts come in different colours. However, the threads are individual and yet still make up the whole. Similarly, the three phases of this research are each distinct, but together, they create a complete story. The investigation into using the device and the lived experiences of women with rectal emptying difficulty helped yield a significant new understanding. This research adopts an explanatory sequential design described by Cresswell (2013) (Figure 5.1).



**Figure 5.1: Explanatory-sequential mixed methods design**

The explanatory element is the quantitative Phase 1, followed by the exploratory qualitative Phase 2. Therefore, the quantitative is the dominant method shaping

and framing the exploratory qualitative element. Cresswell (2013) has other designs, which were considered, but because a real-life problem unorthodoxly drives this research, the explanatory sequential design chosen was considered to be the most practical and logical. The three stages of work forming the study, the exploratory phase, Phases 1 and 2, are illustrated in Figure 5.2.

Theoretical Position	Phases	Study Description	Patient and Public Involvement	Methodology	Conceptual Framework	Implementation of Evidence
	Exploratory Phase	Proof of concept		Preliminary findings on nine self-selected cases		
	Quantitative Phase 1	Intervention of the patient-centred device (n=36)		Pre and post questionnaires Proctogram Biomedical data		
	Qualitative Phase 2	Interpretation of the lived experience		Semi-structured interviews		

**Figure 5.2: Exploratory phase, Phase 1 and 2**

### 5.5 Implementation sequence and mixing

Central to MMR is integrating, synthesising, or mixing of data (Cresswell and Plano Clarke, 2018). Integration, synthesising, or mixing is strengthened within the research study because the Phase 1 and 2 participants are of one group (Fetters *et al.*, 2013). However, how to do this well continues to be a subject of debate (Cresswell and Plano Clarke, 2018, Fetters *et al.*, 2013, Noyes *et al.*, 2019, O’Cathain *et al.*, 2010, Tashakkori *et al.*, 2020, Teddlie and Tashakkori, 2003). For instance, mixing can be facilitated using the concept of triangulation, following a thread, or developing a mixed-method matrix (O’Cathain *et al.*, 2010). More recently, interpretation on synthesising data suggests a convergent or sequential

approach (Hong *et al.*, 2017). Convergent synthesis applies the analysis of the data in parallel, whereas the sequential approach relies on the analysis of quantitative and qualitative data one after the other. The three phases of this research employ a sequential technique to bring them together and provide depth and meaning that none of them alone could supply. Navigating the range of choice for mixing is complicated and should be driven by the needs of the research. Protagonists may argue that integration, synthesising, or mixing is poorly reported, and hence this limits validity and measurement opportunities (Noyes *et al.*, 2019). However, gaining knowledge and understanding in a complex field requires flexibility and real-world methods (Moran-Ellis *et al.*, 2006).

The positioning of Phase 1 before Phase 2 was an iterative decision that arose from the clinical problem driving the need for invention and innovation.

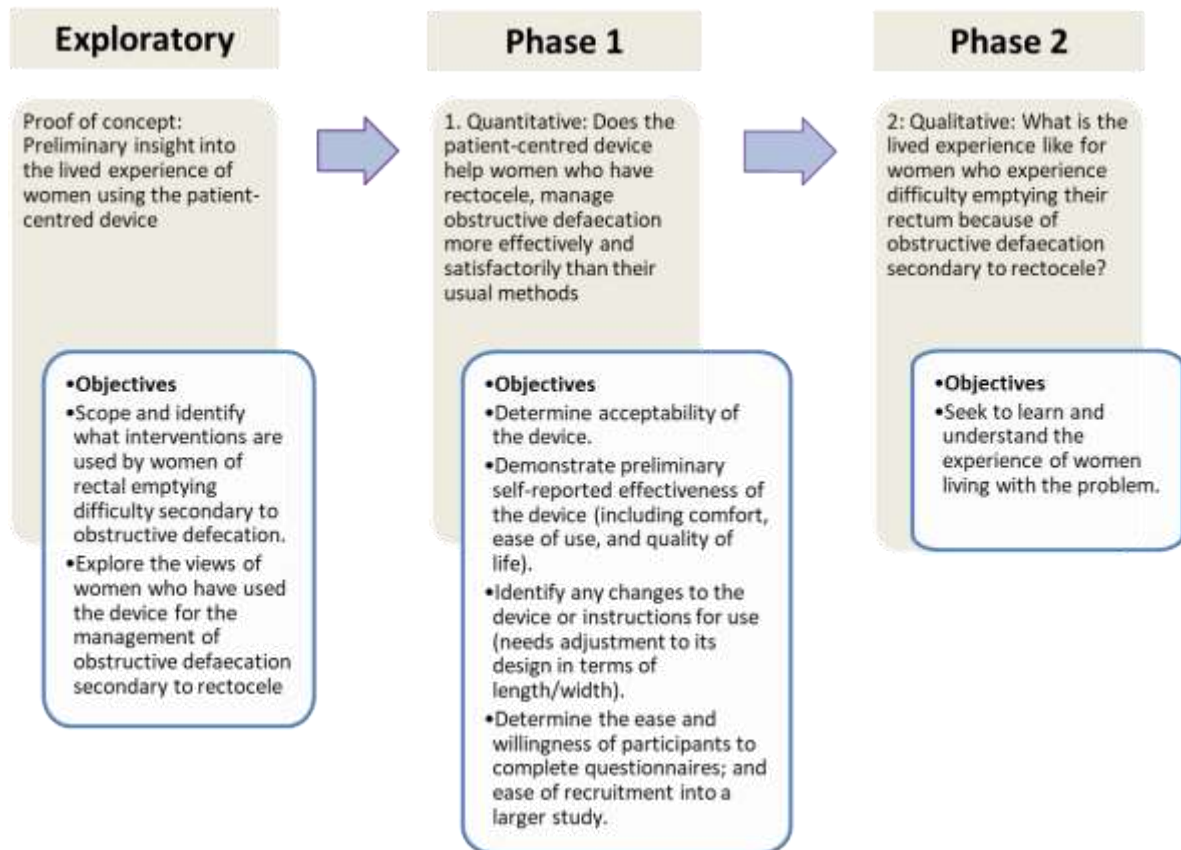
Commencement of Phase 1 identified the extent of untold stories and the need to provide an opportunity for the women to share their stories, which subsequently shaped Phase 2. This pragmatic approach meant that rigour and quality were fundamental in its reporting, including limitations. Fàbreques *et al.* (2021) advise that MMR is 'highly context-dependent' (p.146) and therefore reporting limitations provides additional credibility.

## **5.6 Study aim and objectives**

### **5.6.1 Aim**

The overall aim of this research was to explore factors that influence women's self-management of rectal emptying difficulty. The study consists of three

supplementary aims along with specific objectives for each. Figure 5.3 illustrates how they are linked.



**Figure 5.3: Objectives with the exploratory phase, Phase 1 and 2**

### 5.6.1.1 Supplementary first aim (Exploratory):

To seek a preliminary understanding of the lived experience of women.

#### 5.6.1.1.1 Objectives

- Scope and identify what interventions exist and improve the management of rectal emptying due to obstructive defaecation secondary to rectocele (reported in Chapter 3).
- Explore the views of women who have used the device for the management of obstructive defaecation secondary to rectocele.

### **5.6.1.2 Supplementary second aim (Phase 1):**

A quantitative phase to investigate if the device helps women manage rectal emptying difficulty due to obstructive defaecation secondary to rectocele more effectively than usual methods.

#### **5.6.1.2.1 Objectives**

- Determine the acceptability of the device.
- Demonstrate preliminary self-reported effectiveness of the device (along with comfort, ease of use, and quality of life).
- Identify any changes to the device or instructions for use (needs adjustment to its design in terms of length/width).
- Determine the ease and willingness of participants to complete questionnaires, and ease of recruitment into a larger study.

### **5.6.1.3 Supplementary third aim (Phase 2):**

A qualitative phase to investigate the lived experience for women with rectal emptying difficulty.

#### **5.6.1.3.1 Objectives**

- To gain a deeper understanding of the experience of women living with the problem.

## **5.7 Exploratory Phase**

The exploratory phase aimed to offer insight and clarify proof of concept (Ekins *et al.*, 2017) of a patient-centred device using anonymous feedback from women via their experience of using the patient-centred device to help their rectal emptying. Critically, it was also essential to identify any barriers or concerns with progressing the study. Given that this research was uncharted territory, exploration of what

and how to do the work was fundamental. A description of the exploratory phase in research appears to be lacking, although many studies include exploration as a preliminary element to their work (Swedberg, 2018). Furthermore, three early-stage inventions that had not yet reached the market were discovered through a search for similar devices. As a result, there was nothing on the market to help women cope with digitation before introducing this novel patient-centred device.

The origins of exploratory research are scanty (Swedberg, 2020). That said, Swedberg (2020) offers a valuable insight into the paucity of exploratory research knowledge. He proposes six types of exploratory research (Table 5.1).

**Table 5.1: Swedberg's six types of exploratory research (Swedberg, 2020)**

Type of exploratory research	Goals
Standard exploratory study (Type 1)	Explore a little-known topic Multi-methods Publishable
Standard exploratory study (Type 2)	Develop new hypothesis Substantial sample size Standard methods Publishable
Informal exploratory study (Pre-study)	Develop new ideas Use whatever method suits Small sample size
High-risk exploratory study	Develop innovative ideas where a high risk of failure is present Standard methods
Pilot study or exploratory study used for a research proposal	Research a topic informally to design the dissertation No sample group required
The exploratory study used in student exercises	Theorising essential topics that do not require a methodological approach

For the exploratory phase in this research, the informal exploratory study approaches best matches intention (highlighted row in Table 5.1). However, there are associations with other types, for example, the high-risk exploratory approach because of the invention and innovation of a new patient-centred device, which may not be effective for women. For instance, feedback using the patient-centred device can reveal the women's experiences, which was previously uncharted and undefined. Therefore, it was vital to understand if this new device helped the women and what further in-depth inquiry was required. However, although recognised, the inconclusiveness nature of the exploratory phase did not make it less worthy. On the other hand, conducting this phase, is less specified and may result in an ad hoc approach. By focusing on the problem, establishing the research questions, and clarifying the next step in the journey, robustness and rigour can be achieved (Bhat, 2020).

The exploratory phase focused on women who had decided to self-purchase the device, use it for their rectal emptying difficulty and send back anonymous feedback on their experience. The origin of proof of concept is challenging to distinguish and define (Jobin *et al.*, 2019). However, it was perceived as a validation of an idea or as a check prototype's readiness. Kendig (2016) has considered the challenges that befall proof of concept and provides a valuable interpretation:

The concept is 'proof of concept' appears to refer to any idea that may apply to a class of phenomena. The proof seems to be a possibility proof that is shown to obtain in experimental practice (p3) (Kendig, 2016).

Furthermore, Kendig (2016) suggests that proof of concept is the transportation of knowledge into an experimental stage. In the exploratory phase of this research, the patient-centred device was already commercially available. The feedback analysis contributed to seeking validation for progressing to the subsequent phases.

The development of the patient-centred device included an international intellectual property search for any other device that might already exist to help women with digitation. Additionally, social media commentary further substantiated the importance of this exploratory phase. Social media is a fast-developing source of information lending itself to a deeper understanding of people's views and experiences (Flott *et al.*, 2016). Real-life experiences of women using the device captured via social media platforms offered detection on their use of language. Google searches (Google, 2022) using the brand name for the patient-centred device identified purchase reviews from women (ReviewMeta, 2021). Although the method for this research did not include an examination of these reviews, it is helpful to acknowledge these women when considering real-world insight.

### **5.7.1 Sample selection and recruitment**

The sampling technique was purposive because it provided the best possible cohort of women for study (Etikan, 2016). The nine women were self-selecting and homogenous in terms of their lived experience with bowel difficulty. They sought out the patient-centred device, predominantly via online shopping, then spontaneously completed the device evaluation form, and thus were identified as a sample group.



### 5.7.2 Data Collection

Gathering information from evaluation forms sought preliminary insight into the experience of using a patient-centred device for women with rectal emptying difficulty. Each device package contained an evaluation form (Appendix 6). The form included questions about the characteristics of the individual, their current way of managing their rectal emptying difficulty, detail on their usual management and using the device. Additionally, opinions on their preference for management of the problem, the self-reported effectiveness of the device, including its ease of use, place of use, convenience, and the feel of it (Table 5.2).

**Table 5.2: Evaluation form questions**

Age
How long have you had a rectocele (months)?
Awaiting surgery?
Current management: <ul style="list-style-type: none"> <li>• Do nothing</li> <li>• Use fingers</li> </ul>
Usual care comments
Using the <i>patient-centred device</i> * comments
Preference between usual care or the <i>patient-centred device</i>
Effectiveness ( <i>Very effective, useful, slightly helpful, not at all effective</i> )
Ease of use ( <i>Very easy, easy, acceptable, difficult, very difficult</i> )
Place of use ( <i>only when at home, anywhere I needed to, only at other places whilst out</i> )
Convenience, storage, and carrying ( <i>very convenient, convenient, acceptable, inconvenient, very inconvenient</i> )
'Feel' of the <i>patient-centred device</i>
Any suggestions for improvement

\* the brand name for the patient-centred device was used within the evaluation form

Feedback from nine women who self-purchased the device was obtained anonymously via a voluntarily completed evaluation form. They returned the

completed evaluation form to the Medical Devices Technology International (MDTi) office (MDTi, 2022). The MDTi collaborates closely with healthcare professionals and their organisations to deliver a comprehensive business solution for ideas transformed into practical and commercially viable products. In the case of this research, the MDTi were instrumental to adopting the researcher's invention, with progressing to manufacture. The MDTi office anonymised the evaluation form and emailed a copy in portable document format (PDF) to the researcher.

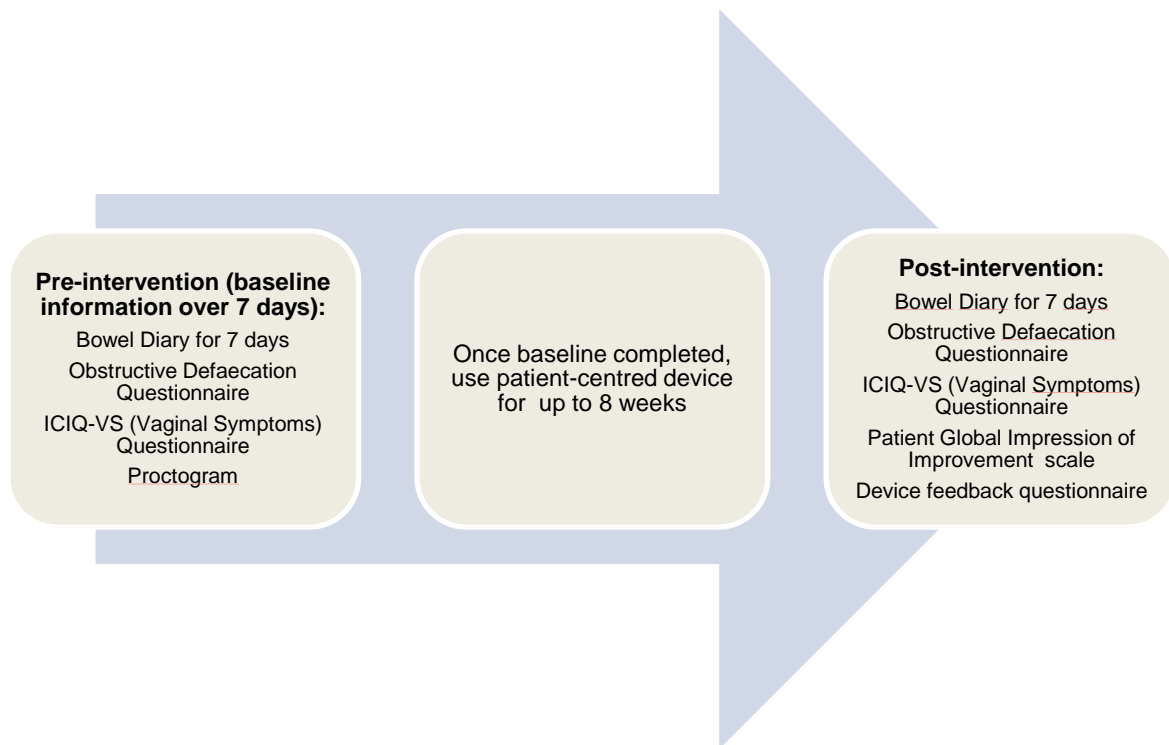
### **5.7.3 Data analysis**

The lived experience information was analysed using thematic analysis (Braun and Clarke, 2006). Braun & Clarke's approach includes familiarising with the data, generating initial codes, searching, reviewing, defining themes, and finally producing the report. The number of questionnaires available for analysis was small, and therefore, data were aggregated using table format in Word for Microsoft 365 (Microsoft, 2022).

## **5.8 Phase 1: Quantitative**

### **5.8.1 Design**

The explanatory sequential design, as described by Cresswell (2013), began with the explanatory element, which is Phase 1. Phase 1 involved a pre-post intervention design (Figure 5.4) in evaluating the preliminary self-reported effectiveness of using the patient-centred device and identify implementation feasibility.



**Figure 5.4: Pre-post intervention design**

### **5.8.2 Phase 1 Research question**

Does the patient-centred device help women who have rectocele, manage obstructive defaecation more effectively and satisfactorily than their usual methods?

### **5.8.3 Sample selection and recruitment**

Purposive sampling (Liamputtong, 2013) was used because of the vital information women with rectal emptying difficulty can supply that cannot be gained as effectively through other routes. Female adults referred to the gynaecology or colorectal services in secondary care with obstructive defaecation symptoms and who required diagnostic imaging (i.e., proctogram) as part of their routine care were invited to take part in Phase 1. Poster information about the study was

available within the secondary care outpatient waiting areas (Appendix 7). The MDTi provided the patient-centred device free of charge for the study.

Women who presented to primary care because of obstructive defaecation symptoms (constipation, soiling, difficulty emptying, and feeling of vaginal pressure or bulge) are most likely to be referred into secondary care (Sugrue and Kobak, 2016). For those not referred into secondary care, primary care intervention focuses mainly on treating constipation with laxatives (Doaee *et al.*, 2014).

Although not necessary for this exploratory research, a power calculation helped to guide how many women to recruit (Su, 2018). Power was calculated assuming two sets of paired data and a two-sided outcome (at the 95% significance level) with a power of 80%, anticipating an effect size of 0.5 (50%) for both the above. The calculation realised that a minimum sample size of 34 would be required, consistent with Machin *et al.* (2018). Thirty-six adult females who met the eligibility criteria were invited via secondary care outpatient clinics to use the device throughout / or up to eight weeks. This purposive sample number had been deemed sufficient to meet the study's objectives. Two of the 36 females were recruited because they saw the poster in the outpatient waiting room within the secondary care hospital (Appendix 7) and asked their medical consultant about joining the study. These women both met the eligibility criteria (Table 5.3), and so the inclusion of these offset some anticipated attrition between the pre-and post-data collection points. Others have pointed out that the sample size for feasibility can be a contentious topic (Julious, 2005, Sim and Lewis, 2012).

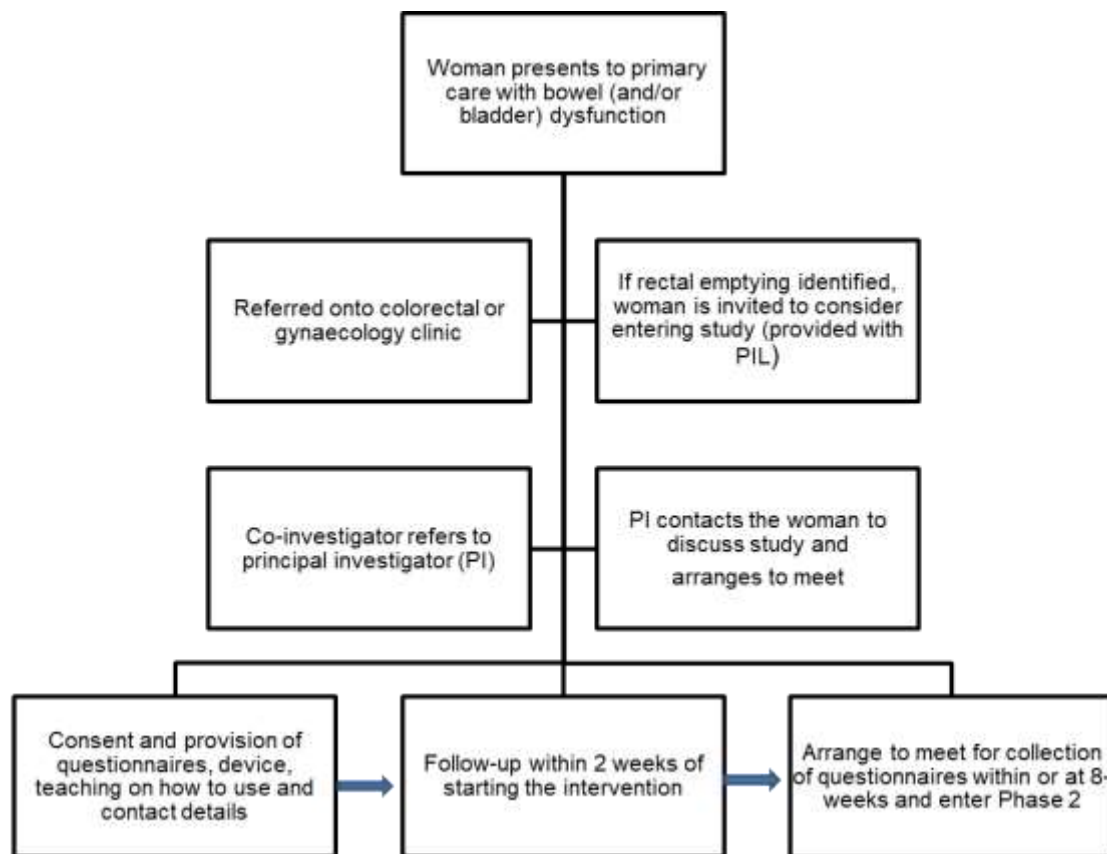
However, for this research Phase 1 did not have a control group, and therefore, the sampling was non-random.

**Table 5.3: Eligibility criteria**

<b>Eligibility criterion</b>	<b>Rationale</b>
<b>Inclusion criteria</b>	
Adult females (over 18 years of age) with symptoms of rectal emptying difficulty	Children and young people are unlikely to experience rectal emptying difficulty in the context of rectocele. Men do not experience this condition due to anatomical differences.
Not undergone posterior vaginal compartment prolapse surgery	Surgery adds factors that may affect use of the device (for example, scar tissue).
<b>Exclusion criteria</b>	
Cognitive impairment	Memory difficulties impact on ability of the participant to engage with the research.
Hand disability	Restricts ability to use the device.
Pregnancy	The device has not been used in pregnant women before.
Less than 12 weeks post-partum	Avoids introducing discomfort for a recovering pelvic floor.
Neurological disease	This is a different cohort of women and outside the scope of this study.

Co-investigators (medical consultants) of the research asked the women referred to their secondary care clinics if they would like to be involved in the study. If they said yes, the women were provided with a Patient Information Leaflet (Appendix 8). For those that wanted to proceed further with the research offer, the co-investigator referred the woman to the researcher (Principal Investigator) to make initial contact. Contact was via telephone, and the women were provided with verbal information on the study. On agreement to continue with the research, another Patient Information Leaflet was offered and sent by post or via email. Thereafter, women who wanted to discuss the study further and get involved contacted the Principal Investigator by telephone or email.

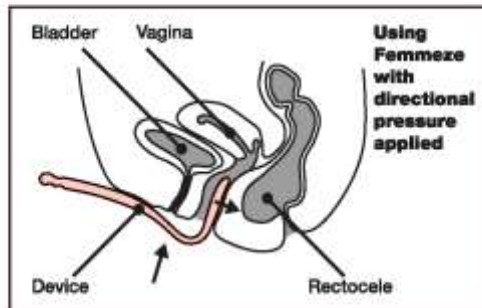
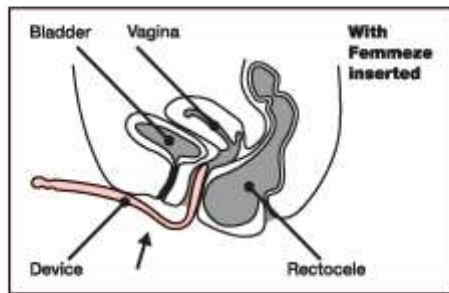
A meeting was subsequently arranged at a location of their choice. At the meeting, the woman was consented (Appendix 9), provided with the composite questionnaires, given the patient-centred device, and taught how to use it (using verbal and written instruction). Teaching was enhanced by access to a four-minute online charity-funded video (Eustice, 2018). Any questions were answered, contact details were provided, and a follow-up date was agreed (Figure 5.5).



**Figure 5.5: Recruitment process for Phase 1**

### **5.8.6 Patient-centred device**

The intervention within this research study is the patient-centred device, a Class 1 medical device, which is single-patient use developed to offer a hygienic and dignified solution to help women discretely self-manage their condition. The device is hand-held and has an L-shaped angled paddle, which is inserted into the vagina (lubricated with a water-based gel) at the time of defaecation. During defaecation, directional pressure is applied via the paddle onto the posterior wall to help the rectum to empty (Figure 5.6). The device is trademarked Femmeze® and is protected by Community Registered Design (Schlotelburg, 2006). The material is acetal that has no toxicity issues when applied internally. Furthermore, it is Food and Drugs Administration (FDA, 2022) and Medicines & Healthcare products Regulatory Agency (MHRA, 2022) medical grade approved material. The device can be reused following simple washing instructions. The device is coloured pink and comes with a velvet-feel black drawstring pouch to store it. On first purchase, the device is packaged within a labelled box, including a user device guide (Appendix 10), evaluation form, and two starter sachets of water-based lubricating gel. Further supply of water-based lubricating gel is self-purchase.



**Figure 5.6: Position of patient-centred device on insertion and its posterior direction on the back wall of the vagina**

### **5.8.7 Data Collection**

The primary outcome of Phase 1 was the self-reported effectiveness of the device for participants with difficulty emptying their rectum because of obstructive defaecation due to the rectocele. Effectiveness in this context refers to the device's usefulness (did it do what it is intended to do). To assist with assessing effectiveness this was measured pre-and post-intervention by using a composite quality-of-life instrument (ICIQ-Vaginal Symptoms; Obstructed Defaecation



Syndrome Questionnaires and PGI-I scales), supported by bowel diary recordings (Appendix 11) and participant feedback on using the device (Appendix 12). The feedback form was similar to the evaluation form used in the exploratory phase. Secondary outcomes were focused on device feedback from the participant by capturing their experiences of preference, effectiveness, ease of use, and convenience of the device. Supplementary data was captured from clinical imaging via a proctogram.

The International Consultation on Incontinence Modular Questionnaire – Vaginal Symptoms (ICIQ-VS) and Patient Global Impression of Improvement (PGI-I) are validated and published questionnaires (Price *et al.*, 2006, Srikrishna *et al.*, 2010). The Obstructed Defaecation Syndrome (ODS) is published but has not been exposed to validation (Longo, 2003). Studies using all three questionnaires have not been located. However, a randomised controlled trial involving 101 women who were randomised to vaginal hysterectomy or laparoscopic sacrohysteropexy to treat uterine prolapse used the ICIQ-VS and PGI-I questionnaires (Izett, 2021), demonstrated their usefulness. Similar to this study, Drage *et al.* (2021) implemented the ICIQ-VS at baseline and at 12-month follow-up in addition to the PGI-I questionnaire. Notably, these measures are subjective but have been used in incontinence and surgical studies because of good repeatability with participants (Srikrishna *et al.*, 2010, Price *et al.*, 2006). Price *et al.* (2006) validated their questionnaire (ICIQ-VS) with 77 randomly selected women in primary care, demonstrating consistency and reliability for vaginal symptoms (Cronbach's alpha 0.79). The PGI-I construct validity was determined by comparing the final PGI-I answer to other response measures at one year for 109

women (Srikrishna *et al.*, 2010). The Obstructed Defaecation Syndrome (ODS) questionnaire (Longo, 2003) has not been subjected to a validation process, yet has been popular in clinical practice and is considered an important scoring system (Sharma and Agarwal, 2012). Most other scoring systems mainly focus on constipation, whilst the Longo questionnaire (2003) concentrates on obstructive defaecation. Therefore, fitting for this study. The bowel diary is a recognised, yet unvalidated, clinical tool common to practice, underpinned by the Bristol stool chart (Lewis and Heaton, 1997). The device feedback questionnaire was not exposed to a validation and reliability process and was developed specifically for the device.

The ICIQ-VS questionnaire (Price *et al.*, 2006) assesses the consequence of vaginal symptoms on quality of life, covering vaginal symptoms (scores 0-53), sexual matters (0-58), and quality of life (0-10). A lower score signifies less consequence of symptoms. For this study, question 8a was selected as a primary outcome measure 'Do you have to insert a finger into your vagina to help empty your bowels?'

The ODS eight-item questionnaire (Longo, 2003) examines the severity of obstructive defaecation. The range of answers is 0 (best) to 24 (worst), covering medication, difficulties with evacuation, digitation, needing to return to the toilet, straining, time, and lifestyle alteration.

The Patient Global Impression of Improvement (PGI-I) scale, a seven-point scale, has received support within gynaecology as a helpful measure within prolapse

surgery (Srikrishna *et al.*, 2010). The advantages of using a seven-point scale compared to a five-point scale are inconclusive (Weijters *et al.*, 2010). However, the PGI-I scale is ready-made, easy to use, and applicable to the research. Its application to this research draws upon its utility as capturing participant response in the context of the patient-centred device. Although outside the scope of where the questionnaire has been used before (incontinence and prolapse surgery), the appeal of ease and practicality suited the research, which was upheld by expert colleagues in the field (Tincello *et al.*, 2013).

Clinical imaging data via proctogram provided information on rectocele size (small, medium, or large), trapping of contrast paste, and extent of perineal descent. Proctogram is a ‘...functional, real-time assessment of the mechanics of defaecation in a physiologic setting’ (p.420) (Brennan *et al.*, 2008) that uses a viscous barium paste into the rectum and images its subsequent evacuation (Sultan *et al.*, 2016). The imaging identifies if contrast paste is trapped within the rectum. Perineal descent, defined as the distance moved by the perineum below the anal canal opening, is considered abnormal if it exceeds 3cm (Brennan *et al.*, 2008). Imaging reporting specifies if the perineal descent is limited or excessive. Proctogram invitation was initiated by the secondary care consultant as part of the woman’s usual care pathway and accessed via the local secondary care hospital. If the woman chose not to have the proctogram, they were not excluded from the study. Therefore, some women were recruited to the study already having their proctogram, and others were waiting for it when recruited.

All participants who gave signed informed consent completed the seven-day pre-intervention baseline information (before using the patient-centred device)

involving:

1. Quality of life instrument (ICIQ-Vaginal Symptoms <http://www.iciq.net/ICIQ-VS.html>) (Price *et al.*, 2006) – permission was sought from the authors to use this questionnaire.
2. Obstructed Defaecation Syndrome Questionnaire (Longo cited in (Sharma and Agarwal, 2012).
3. Bowel diary (using the Bristol Stool Form Scale) (Lewis and Heaton, 1997)

Following pre-intervention baseline information, the participants used the device for up to an eight-week intervention period and followed up prospectively to compare the device against their usual care. Usual care in this context was the method that the participants chose to help empty their rectum of stool. Methods include using their fingers or doing nothing.

Participants were invited to stop using the device if they no longer wished to continue, found it too uncomfortable, did not like the device, or because it had no effect on their symptoms. At the end of the pre-intervention baseline information period, all participants (including any dropouts) were asked to complete the following questionnaires:

- Quality of life instrument (ICIQ-Vaginal Symptoms <http://www.iciq.net/ICIQ-VS.html>)
- Obstructed Defaecation Syndrome Questionnaire
- Bowel diary (using the Bristol Stool Form Scale)

- Patient Global Impression of Improvement (PGI-I) scale (Srikrishna *et al.*, 2010)
- Device feedback questionnaire

Participants were invited to keep the patient-centred device at the end of the eight weeks to continue to use it if they so wished.

### **5.8.8 Data Analysis**

The focus of the data analysis was to measure symptom improvement using the device. Demographic and pre-intervention baseline data (Table 5.4) were reported using the mean and medians for continuous data and percentages and counts for categorical as appropriate. The primary outcome data of the pre-and post-questionnaires were compared using the Wilcoxon Signed Rank Test (Woolson, 2007) and conducted to evaluate whether a statistically significant difference existed between the pre- and post-intervention response to Question 8a, along with primary data from the ODS questionnaire and bowel diary. Significance levels and effect size are reported in the results. Effect size was based on Cohen's convention criteria measured as 0.1 = small effect, 0.3 = medium effect and 0.5 = large effect (Pallant, 2020, Cohen, 1988). Because participants were measured on two occasions (pre and post), non-parametric data were suited to a distribution-free test (Pallant, 2020). The secondary outcome of feedback questionnaire data was reported using percentages and counts of responses. Supplementary data on the proctogram imaging was reported using percentages and frequencies. Missing data were reported but not thoroughly investigated, although aided understanding the reasons and informing acceptable conclusions. However, only available data was analysed. Any free text responses

were manually coded and analysed using thematic and framework analysis (Braun and Clarke, 2006, Gale *et al.*, 2013). Reporting of categories were combined for small numbers.

**Table 5.4: Data collection and analysis**

<b>Data collection</b>	<b>Tool</b>	<b>Analysis</b>
Demographic and other pre-intervention characteristic information	Baseline form	Range, mean, and frequency
Score at pre-and post-intervention	Quality of life instrument (ICIQ-Vaginal Symptoms <a href="http://www.iciq.net/ICIQ-VS.html">http://www.iciq.net/ICIQ-VS.html</a> )	Wilcoxon signed-rank test
Score at pre-and post-intervention	Obstructed Defaecation Syndrome Questionnaire	Wilcoxon signed-rank test
Chart	Bowel diary	Wilcoxon signed-rank test
Measurement (at post-intervention only)	Patient Global Impression of Improvement (PGI-I) scale	Range, mean, and frequency
Questionnaire	Device feedback	Range, mean, and frequency
Measurement (at pre- or during intervention only)	Proctogram	Range, mean, and frequency

Early in the study, a quality check of the data was initiated from the first seven completed composite questionnaires, and bowel diary entries were extracted and added to a data entry spreadsheet in Excel 2010 before uploading to Statistical Package for the Social Sciences (SPSS) (IBM SPSS 25, 2017). A data entry check was completed, and any errors were corrected. Non-return of questionnaires was treated as missing data.

All participants were enthusiastic about commencing using the device. As such, there was concern that they may skip the pre-intervention baseline information

stage, in eagerness to start. A one-page guidance sheet was created for participants to refresh their memory at any point during the study (Appendix 13). The Principal Investigator contacted each participant within two weeks of commencing the study to answer any queries or concerns.

#### **5.8.9 Adverse events/patient safety**

Following the intervention period, participants continued their clinical journey, as they would have done without using the device. Those participants who continued to use the device beyond the study period were invited to access regular consultation clinics with their specialist clinician as per local standard care pathways.

A potential risk was discomfort from using the device. Participants were advised that should they experience this, they were to stop using it immediately and notify the researcher, who would seek to understand why this had happened via sensitive questioning and completion of the device feedback questionnaire. The device is Class 1 CE registered, which means it is classified as the lowest perceived risk (MHRA, 2020). Reporting of all adverse events were to MHRA (MHRA, 2022) and the MDTi.

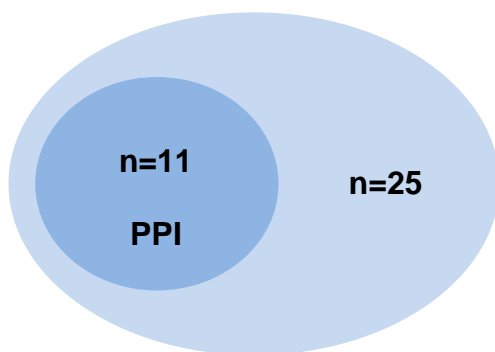
#### **5.8.10 Public and Patient Involvement (PPI)**

Establishing a PPI group effectively is underpinned by specific National Institute for Health Research information (INVOLVE., 2012). Setting up a group is not easy, for instance, when and where to meet and maximising attendance. Skilton *et al.* (2016) offer an unusual and rare insight into setting up a PPI group, although not necessarily representative of areas with less infrastructure to support sustainability. A more helpful perspective is obtained in Hyde *et al.* (2016), who

presents transferable recommendations, aligning with local resources and good meeting conduct.

During Phase 1, it became apparent after the first eleven women were recruited that PPI was critical to establish and involve the participants in shaping the study (Skilton *et al.*, 2016). Although the PPI was not set before the start of the study, which was a key learning point and missed opportunity, the unintentional delay lent itself to a better progression. These first 11 participants became the PPI group. The PPI group provided clarification in a timely and illuminating way. Bringing together the 11 participants from Phase 1 into a PPI group who had used the device was central to Phase 2. Furthermore, the revelation of the hidden suffering and feelings of isolation enabled a rethink of how practice can be improved.

The information gathered from the first 11 participants provided the first 'interview' and was included in the analysis. The remaining 25 were invited to an individual interview (Figure 5.7).



**Figure 5.7: Number of participants within PPI and non-PPI**



The establishment of a PPI group assisted with the development of Phase 2. The output from the PPI group raised questions about Phase 1, for example, recruitment; and developing Phase 2 methods, with members advising on three areas for improvement. Firstly, it was appropriate and ethically correct to use the information from the PPI group to inform the research journey considering their in-depth contribution to lived experience. Secondly, the opportunity to further explore the participant's experience of living with the problem and gaining a deeper understanding of being part of the study was weak within Phase 1. Finally, the group suggested that a poster be used within waiting areas to boost recruitment to the study so that potential participants or women searching for help could be empowered to enquire further at their consultation with the secondary care consultant. The recommendations from the PPI group formed a resubmission to NHS Ethics and were subsequently approved.

## **5.9 Phase 2: Qualitative**

The purpose of Phase 2 was to inquire into and search for the meaning of the participants' experience (Kvale and Brinkmann, 2009).

### **5.9.1 Phase 2 Research question**

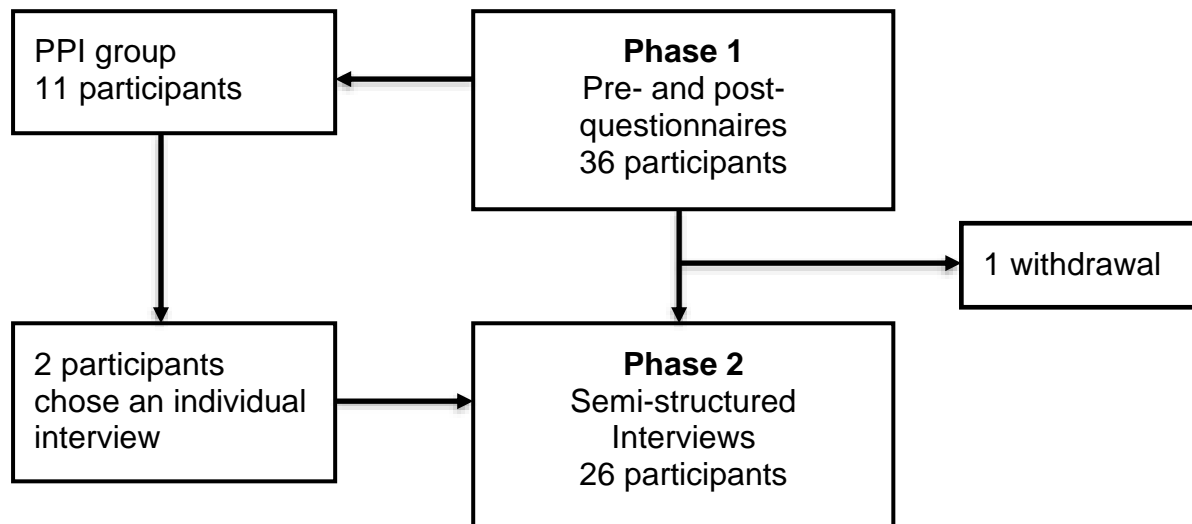
What is the lived experience like for women who experience difficulty emptying their rectum because of obstructive defaecation secondary to rectocele?

### **5.9.2 Sample selection and recruitment**

Participants in Phase 2 were from the same sample as Phase 1. Twenty-five participants in Phase 1 were invited to an interview (these excluded the first 11 participants since they formed the PPI group). Nine of the 11 participants from the

PPI group contributed towards the data collection as a 'group'. Two participants of the total 11 members of the PPI group chose to have an interview (Figure 5.8).

The participant (n=1) who withdrew from Phase 1 was also invited to interview but declined.



**Figure 5.8: Phase 2 interview participants**

### 5.9.3 Data Collection

Kvale and Brinkmann (2009) provide a constructive seven-step framework for complying with interview good practice. The interview provided a vital narrative to improve understanding of the rectal emptying problem faced by women. The PPI members influenced and guided the interview schedule and agreed the following topics be explored:

- I. Living with the problem
- II. Using the patient-centred device
- III. Being part of Phase 1

Interviewing skills were necessary to effectively capture the women's experience (Dempsey *et al.*, 2016). Even though the semi-structured interview schedule provided a format (Appendix 14), it was used flexibly and only for prompts as needed. Giving space and time for the woman to share her experiences added depth and richness to understand their lived experience (Cheng *et al.*, 2003). If emotional distress emerged or a break was necessary, the interview was halted and resumed at a convenient time for the participant. Eleven of the women had already shared some of their experience through PPI involvement and two chose an individual interview. Relationships with the participants who had an individual interview were developed further than those who had been involved with the PPI group, which needed to be considered. One issue that arose was the blurring of role boundaries. Distancing the researcher's role from giving therapeutic advice within an interview required careful attention and reflection (Bolton, 2010).

The interview was up to one hour in length, guided by the interview schedule (Appendix 14), which was informed primarily from the PPI group feedback and also the literature (Alam *et al.*, 2017, Brown *et al.*, 2017, Vrijens *et al.*, 2017, Jelovsek and Barber, 2006). The interview was conducted in a location convenient to the participant, which allowed for minimal interruption. A glass of water and tissues were made available, given the sensitive nature of the interview. Most preferred an NHS setting in a location close to their hometown. None of the participants chose to have the interview in their own homes. Participants were advised to bring along a chaperone should they wish to. Recording of the interview was via an Olympus digital dictation machine (model WS-853), with the capability of media file download onto an NHS laptop computer and was

transcribed contemporaneously. This facilitated learning from and refining the interviewing technique ready for the subsequent interview. For example, the researcher recognised the tendency to fill in silences and increased reflective questioning.

Opening the interview included a question from the researcher “*Please tell me about your experience of living with difficulty with emptying due to your rectocele*”. The participant guided the conversation using prompts and probes where needed. Where participants diverted away from the topic, the researcher gently brought them back when the diversion did not lead to relevant discovery. Should the participant become distressed, the interview would have been aborted and rescheduled if the participant consented. Concluding the interview occurred when no further information was forthcoming, or the participant had naturally finished what she had to tell. The researcher finalised the interview by asking ‘*Is there anything else you’d like to tell me*’ and thanked them for their time.

#### **5.9.4 Data Analysis**

The Framework Method was chosen as the preferred approach because it facilitates themes and patterns of meaning (Gale *et al.*, 2013). Selecting the analysis approach identified the variety available for researchers (Table 5.5). Other methods were considered and excluded, such as grounded theory analysis (Glaser and Strauss, 2017), social network analysis (Scott, 2017), conversation analysis (Wetherell, 1998), and narrative analysis (Charmaz and McMullen, 2011).

**Table 5.5: Discounted analytical approaches**

<b>Analytical approach</b>	<b>Focus</b>
Grounded analysis	Builds on a central phenomenon
Social network analysis	Identifies links between individuals
Conversation analysis	Assumes that conversations have rules and patterns which remain constant whoever is talking
Narrative analysis	Focuses on an organisation or society to deepen understanding of how people think and organised within groups
Thematic Analysis	Identifies themes and patterns

Following exclusion of these analytical options, thematic analysis was initially assigned as the best fit, because it allows detailed description (Braun and Clarke, 2006). Thematic analysis from the perspective of Braun and Clarke assumes six phases (Table 5.6), which offer flexibility and a less complex approach. The data need to speak with richness throughout identifying, analysing, and interpreting. That said, the thematic and framework method of analysis share similar methodology in their systematic approach to working with qualitative data (Smith and Firth, 2011). A thematic analysis approach (Braun & Clarke, 2006) was considered, as it lends itself well to lived experience and allows flexibility (Cresswell, 2013). However, the attraction of the Framework Method (Table 5.6) is the depth and linkages that can emerge, providing a compelling approach for using NVivo (Gale *et al.*, 2013, Kiernan and Hill, 2018) and judged more fitting for this study.

**Table 5.6: Thematic and Framework Analysis Similarities**

<b>Thematic Analysis (Braun and Clarke, 2006)</b>	<b>Framework Method (Gale <i>et al.</i>, 2013)</b>
	Transcription
Familiarising yourself with your data	Familiarisation with the interview
Generating initial codes	Coding
Searching for themes	Developing a working analytical framework
Reviewing themes	Applying the analytical framework
Defining and naming themes	Charting data into the framework matrix
Producing the report	Interpreting the data

Based on Gale's seven-step approach, data were analysed in the following way:

Step one and two: transcription and familiarisation of the interviews

Recording the interview and transcription were quasi-anonymous: the interviews were transcribed in full and identifying features were removed from the transcripts. Each media file was transcribed into a Word document, and each document was formatted for NVivo 11 using word styles. Once uploaded to NVivo 11, nodes were drawn from participant responses, along with manual coding, immersion into the data enabled descriptions to be revised. QSR International's NVivo 11 qualitative data analysis software (QSR International, 2016) was used to manage the transcripts. Twenty-six interviews and PPI meeting notes were transcribed; thus, twenty-seven transcriptions were submitted to NVivo software. Each transcription was read to develop a feel of the story emerging. A priori concerns, living with the problem (mechanical problems, physical effects, and psychological impact), using the patient-centred device and being part of the study, were considered part of the interviewing process and helped the emerging themes.

Listening again to the interviews helped validate the themes that emerged in Phase 1, which shaped the semi-structured interview sheet. Furthermore, it was useful to note anything of significance (e.g., silences and participants' difficulty articulating what they were feeling).

### Step three: coding

A combination of NVivo and manual coding enabled themes to emerge. The initial coding of each transcript with NVivo was transferred to a paper card (one code per card) and laid out manually to see what story they were telling. When the initial grouping of themes emerged, they were revisited to allow for further judgment and refinement. Themes and their aligned codes were adjusted in NVivo to enable robust data organisation.

And independent assessor (not a subject specialist) reviewed the themes and codes to provide a sense check, especially as the researcher was so close to the data (inventor, clinician, and researcher). Any blurring of codes was discussed and clarified following an independent coding of five transcripts. For example, 'bullying and abuse' was added to the theme of 'consequences' following discussion. Additionally, one comment had not been coded. However, the comment *"I'm aware of my anatomy because of the job I do being a midwife you know I just knew that that would help so that's why"* was coded into 'knowledge' following discussion.

#### Step four: Developing a working analytical framework

Both a priori concerns and emergent themes contributed to the framework, enabling the researcher to also be incorporated and remain faithful to the participant story. NVivo software provided a framework matrix facility, which populated the x-axis with the theme and the y-axis with codes. The cells illustrated the participant quotes.

#### Step five: Applying the analytical framework

The text was coded intuitively from the transcript, with a similar approach. Codes were then reviewed and refined at a second exploration. NVivo allows for the drag and drops option for coding. Codes were amended as further exploration refined the meaning of the text.

#### Step six and seven: Charting and interpreting data

Use of paraphrasing where necessary but remaining with the participant's own words to maintain colour and richness of their experience.

### **5.10 Ethics Considerations**

As the exploratory phase utilised anonymous product feedback data, no formal ethical approval was required. Rather the ethics committee was notified of this data usage and no concerns were raised since the information provided contained no identifiable information. For Phases 1 and 2, ethical approval was received from NHS REC (15/SW/0107) and the Faculty Research Ethics Committee (Sept 2015/Reference Number: 14/15-456).



### **5.10.1 Beneficence and Non-Maleficence**

Participants should not be exposed to a procedure they would not usually have as part of a research study unless the benefits outweigh the burden (Beauchamp and Childress, 2001). For this study, participants underwent a proctogram as part of routine care. However, following discussion and approval from local clinical imaging scientists, an additional sequence was added to the proctogram procedure (sequence 3 in the proctogram measurements flowchart; Appendix 15). Participants were women who required a proctogram as part of their routine care within the secondary care setting. There was sufficient benefit gained because the information was used to yield detail on the anatomy and give feedback on how the device works to reduce faecal trapping.

A second ethical consideration was the point at which the device could be added as an option to the range of existing interventions. An example is offered in a constipation standard pathway (Appendix 16). At the stage of introducing suppositories, enemas, or rectal irrigation, the device would provide an additional option. This option could be made available within the primary care setting or from the local specialist services before referral to secondary care. Therefore, the device could potentially be introduced to women at any stage of their journey, depending on personal preferences and clinical recommendations.

### **5.10.2 Informed consent**

Consent forms were stored separately from data collection materials. Participants were advised that data would be anonymised and that no individual participant names would be reported. A master list of participant names was kept separate from the data. Data will be held for up to ten years in a locked and secure

environment following the completion of the study in line with the University of Plymouth Code of Research Practice (2018).

### **5.10.3 Investigator role**

Ethical responsibility includes the investigator's role and autonomy. Being a researcher, inventor, and clinician for this research challenged two key factors: positionality and selection bias. Firstly, positionality is essential to consider (Hopkins, Regehr, & Pratt, 2016) regarding the confusion this can place on the participants and the researcher. As well as being the inventor of the device, the researcher was also involved in the recruitment of participants, data collection, data analysis, and the provision of clinical advice during the intervention period, all of which requires caution. A multi-role can easily influence bias and introduce contamination. Therefore, reflection on this position was vital. While this position does offer benefits in understanding the context and culture, the disadvantages need exploring. For example, participants may not feel they can be open and honest. Furthermore, researcher sympathy with the subject matter and a failure to see the obvious are clear risks. Mitigating these risks was helped by reflective practice and making it clear to participants about the role (for example, at the start of each interview in Phase 1, the role context of a researcher was clarified; Appendix 14). Allowing enough time at the initial meeting with the participant to guide them through the questionnaire completion before and after using the device, and how to use the device was crucial for the participant's understanding. Secondly, selection bias is an equally vital factor to consider (Pannucci & Wilkins, 2010). For example, all women sequentially recruited from secondary care had experienced rectal emptying difficulty secondary to obstructive defaecation. However, this sampling had the potential to miss a large group of women who did

not reach secondary care because of primary care involvement only; or they may be hidden from healthcare, as they do not present due to feelings of embarrassment or do not know that they can. This is noted later as a limitation of this research.

#### **5.10.4 Public and Patient Involvement (PPI)**

It was considered ethically just and right to use the information from the PPI group to inform the study journey considering their in-depth contribution to lived experience. The participant's experience of living with the problem and gaining a deeper understanding of being part of the study was weak within Phase 1, thus PPI created an opportunity to explore this further. Empowering the group discovered ideas for implementation. For example, they suggested that a poster (Appendix 7) be used within waiting areas to boost recruitment to the study so that potential participants or women searching for help could be empowered to enquire further at their consultation with the secondary care consultant.

### **5.11 Establishing Rigour**

*'We don't abandon our pursuits because we despair of ever perfecting them.'*

Epictetus, Discourses, 1.2.37b (Long and Spalding, 1904)

#### **5.11.1 Phase 1 Quantitative: Validity and Reliability**

Enhancing validity and reliability is critical for research integrity (Table 5.7) (DuBois and Antes, 2018). This research set out to understand what the lived experience is like for women with difficulty emptying their rectum. Achieving this understanding favoured the mixed method approach to dive into a hidden world. The world explored, involved asking women to use a device as a novel alternative to self-digitation but creating an opportunity to reveal what it is like to live with the

problem. Revealing their world utilised composite questionnaires that asked directly what effect the device had on their symptoms before and after.

**Table 5.7: Strengths and weaknesses for validity and reliability**

<b>Validity and reliability</b>	<b>Strengths</b>	<b>Weaknesses</b>
<b>Enhancing validity</b>	Consistent sampling and recruitment of women Validated questionnaires used before and after the intervention.	ODS questionnaire has not been through a validation process. The device feedback questionnaire was bespoke and unvalidated.
<b>Enhancing reliability</b>	Consistent application of the method steps by one researcher. All participants were exposed to the same information and conditions.	Multi-role researcher.

The literature is rich with interpretations of how best to enhance research integrity (Polit and Hungler, 1994, Cresswell and Plano Clarke, 2018). One unique perspective is the work of Kraemar *et al.* (2013), who investigated what it means for a researcher (professional or community) to conduct community-based participatory health research. Encouragingly, Kraemer *et al.* (2013) suggest that flexibility is a necessary quality to meet community needs, which has been an essential characteristic in this work. However, direct research contact may weaken the integrity and increase ethical challenges (Yanos and Ziedonis, 2006). That said, Yanos and Ziedonis (2006 p.249) also offer reassuring suggestions that the ‘double-agent’ nature of the researcher and clinician helps bridge the worlds of research and clinical practice. Reassuring though their words are, a triple-agent approach is not mentioned in the literature. Therefore, care must be taken when

considering the most appropriate research designs for those clinicians who integrate several roles.

### **5.11.2 Phase 2 Qualitative: Trustworthiness**

Trust in qualitative inquiry cannot be assumed, and it has to be earned say Stratford and Bradshaw (2016), who emphasise the need for unambiguous interpretation and robust evaluation. They are proponents of Lincoln and Guba's work (1985), whose approach to trustworthiness is anchored in four critical criteria, credibility, transferability, dependability, and confirmability. Justification against each criterion is therefore essential.

#### **5.11.2.1 Credibility**

The research questions generated a design that best answers them by giving direction through a mixed-methods approach and thus offering plausibility.

Substantiation is via prolonged engagement (Lincoln and Guba, 1985), whereby exposure to women in the healthcare setting is most likely to reveal the problem.

The intimacy of clinical consultations, especially in the field of bladder and bowel dysfunction, can expose embarrassing and stigmatised issues. These issues

require sensitive handling, necessitating an emotionally intelligent approach

(Carragher and Gormley, 2017). Furthermore, this research is founded on clinical knowledge and experience, which has tended to draw on theory from existing

bodies of knowledge. However, there appears to be a body of knowledge

missing in the rectal emptying difficulty associated with how women live with this.

Thus, the importance of understanding the psychology of presenting cases and helping to untangle the interwoven physical, emotional, and social elements are

worthy and deserve attention. Separating these elements provides an opportunity to improve healthcare by deepening understanding of the problem (Kitson *et al.*,

2008, Holahan and Moos, 1986, Trew, 2011, Lazarus and Folkman, 1987, Roth and Cohen, 1986) and develop new understanding through this project. Exploring a more profound understanding has influenced reflective practice and continuing professional development. Additionally, the identification of the clinical problem, constructing this into research inquiry, gathering and interpreting data, have been influenced by human interest. As a result, aligning with a predominantly interpretive approach.

#### **5.11.2.2 Transferability**

Limitations of the research are presented in section 9.9, and therefore, future researchers can avoid making generalisations. Importantly, given the nature of the pioneering research journey into a hidden world, it was necessary to interview the right people to extract a sense of what they are experiencing. As highlighted by Tobin and Begley (2004) there is no correct way to conduct interpretation, and therefore full description is essential. In the context of this research, the right people were women with rectal emptying difficulty. As described earlier, a purposive sampling procedure ensured that the participants were representative of rectal emptying difficulty experience. Accessing these women via the clinics where women are referred was pragmatic and logical. Although the number of participants was small, the sample provided an in-depth insight into their world. In Forero *et al.*'s (2018) work on applying trustworthiness criteria in their explorative study of Emergency Department staff experiences, they focus on transferability in the sampling method and data management. For this research, interview transcripts were managed systematically using the NVivo coding software programme (QSR International, 2016), and five of the transcripts were subjected to independent review. Therefore, given the specific cohort of women

included in the study, it could be suggested there is typicality of symptoms and experience. However, caution is advised when generalising to other situations. In contrast to generalisability, transferability of a health intervention into practice has more resonance for this research. Schloemer and Schröder-Bäck (2018) considered via their systematic literature review of 37 papers, how to explain this mechanism. Whilst their review highlights the complexity of transferability, a key message is a need for sufficient description to improve the value of evidence regarding the population, the intervention, environmental circumstances, procedures, and results.

### **5.11.2.3 Dependability**

It is critical to understand where the journey began to ensure that the findings of this research can be replicated if future researchers follow the same approach. The iterative journey of this research included a scope of the literature to establish what is already known of available interventions to help women with rectal emptying difficulty. Although there was an existing context for the new intervention, it was not apparent that it would be suitable or effective for women. Moore *et al.* (2015), in their discussion on process evaluation, highlight the unpredictability of implementing a complex intervention and to be careful about making assumptions. Making provisions for assumptions included the avoidance of relying on one theoretical position. Thus, the research drew upon three theoretical positions that stretch across a chronology of bowel mastery loss and achieving mastery, which provided multiple lenses. The theories are posited on the individual psychological perspective and not organisational theories to facilitate more comprehensive implementation. A critical factor for theory choices

is reinforced by the need to initially understand individual's context. Without such, the influences for women and their experience would be missing.

A further vital component of dependability (Tobin and Begley, 2004) was the collection and analysis from interviews of 26 women was consistent. An anonymous and confidential track record via field notes was kept of interviews which detailed initial thoughts and suggestions for the following interview. For example, during the sixth interview, the researcher commented:

*Challenging to keep the participant flowing – tended to dry up and unsure of her own thoughts...pragmatic and something that had to be done. Almost as if she hadn't any position on it.*

Keeping additional references to facilitate a more detailed description of interviews is necessary, according to Forero *et al.* (2018). Similarly, Tobin and Begley (2004) recommend an audit trail helps establish dependability by allowing others to check the researcher's documentation of facts, techniques, decisions, and the final creation.

#### **5.11.2.4 Confirmability**

When considering reflexivity, there is an opportunity to become a witness to one's behaviour and thoughts. One self-observation, for instance, is a delay in making contact at the two-week point with participants. The reason for making contact is to check out any concerns or queries they may be experiencing. In dealing with their problems or queries, the roles of researcher, clinician, and inventor are all drawn upon. This multi-role, whilst offering richness, can affect clarity. Reflecting on the delay in contacting participants, has demonstrated fear of failure. This fear appeared to be grounded in wanting the device to succeed, thus being afraid that the device would not do as intended. Mitigating this risk included breeding self-awareness, listing daily tasks to be completed, and research supervision.



Fear and blurring the boundaries and saturation, can impact researcher identity (Wray *et al.*, 2007). Although Wray *et al.*'s (2007) work focus on inexperienced researchers in qualitative investigation of women's gynaecological cancer, there are parallels with other contexts with research activity. They argue that debriefing is a crucial need for researchers. Debriefing sounds wise. Especially when seeking to understand how procrastination, research conduct ability, and enhancing rigour can help a study stay untarnished (Schraw *et al.*, 2007). Therefore, critical self-review provides an opportunity for self-development and being a better researcher. Learning is as much about the researcher and other roles, as is the methodology and methods of this research. Self-awareness of procrastinating could be viewed negatively. However, is there a position that supports procrastination to facilitate open thinking and in essence, become more creative. Creativity is supported within post-positivism and perhaps procrastination is one of the vehicles to reach this point (Kim *et al.*, 2017). The turbulent journey of progressing this research points to elements of anxiety. Anxiety can lead to being overcritical and yet disabling progress. Understanding these peaks and troughs of emotions can deepen insight. Stepping back every so often to reflect on the complete work is worthy. Supervision meetings and reflective notetaking assisted with self-direction. Take digitation as an example; for some women, the benefits of digitation outweigh using an alternative. Pre-conceived ideas were that an alternative would always be a better option that needs careful consideration. Finger use is proprioceptive, which cannot be obtained from a technology in the same way. Knowing how much directed pressure to apply involves a sense of knowing, and for some women, routine

treatment may provide better control. As a result, it's critical to think about getting this information from the participants.

Member checking, also referred to as validation of participant involvement, helps to enhance the confirmability of the findings (Birt *et al.*, 2016). The PPI element of this research facilitated checking out with participants in the early stages of the work. However, throughout the research, participants were hard to reach.

Despite telephone contact and email communications, few got back in touch once the interviews had been completed. Understanding this better may be revealed in future research investigations. The challenges of member checking are brought to light by Carlson (2010) who provides a candid view of the trials and tribulations of getting it right. Getting it right does not assume one method of gathering their interpretation of the data. However, acknowledging the function of member checking offers strengthened validity and an opportunity for reflection.

## **5.12 Summary**

This chapter has explained the design and method of investigating rectal emptying difficulty due to obstructive defaecation, secondary to rectocele in a sample of women within an English county in the United Kingdom. The investigation focused on two components, firstly using a patient-centred device compared to their usual care in managing the rectal emptying difficulty. Secondly, how these women (same sample) live with the experience of rectal emptying difficulty. The choice for mixed-method research (MMR), which adopted an explanatory sequential design has been explained, and how it was developed and conducted in each of the three phases (exploratory phase, Phase 1 and 2). The tapestry weaver in a similar context will be satisfied that the loom has all the components

for their art. The next chapter will summarise the key results from the exploratory phase.

## **Chapter 6 Results: Exploratory Phase**

### **6.1 Introduction**

The results of the exploratory phase are reported in this chapter. At this stage, the weaver is aware that the recipient of the tapestry will see beauty, but only they know the chaos of the warps and wefts concealed from view. Likewise, the exploratory phase, utilising feedback given by a small number of women following their purchase, set out to offer proof of concept and unmasking of the lived experience of women using a patient-centred device, whilst identifying any barriers or concerns with progressing the study. Thus, providing confidence that progressing with Phase 1 and 2 would be worthy and are essential. The objectives were to:

1. Scope and identify what interventions exist and improve the management of rectal emptying due to obstructive defaecation secondary to rectocele (reported in Chapter 3).
2. Explore the views of women who have used the device for the management of obstructive defaecation secondary to rectocele.

Searching for similar devices identified three early-stage inventions, which had not reached the marketplace (Klein and Couturier, 2006, Jao and Lee, 2006, Maaskamp *et al.*, 2014). Therefore, before introducing this new patient-centred device, there was nothing similar on the market to help women cope with digitation.

### **6.2 Description of the sample**

The number of eligible cases was 700, which were all those who had self-purchased the device online. Online platforms included Amazon (Amazon, 2022)

and the MDTi (MDTi, 2022). However, the only information provided through feedback came from nine cases over three years. These data from the nine cases (eight via questionnaire and one via letter) had been received by the MDTi. The feedback was provided voluntarily by women who had purchased the patient-centred device within the UK. The age range was 37 and 73 years (mean age 56 years).

### 6.3 Findings

Self-identified symptomatic rectocele was present for a range of nine months to 45 years. All the women used an intervention. Most of them (n=7) used only their fingers as their current management and other interventions included laxatives, enemas, and a vibrator (Table 6.1). Two women reported that they were waiting for surgery. Case 4 wrote a letter instead of completing the questionnaire.

**Table 6.1: Age, duration of rectocele, and current management**

Cases	Age	Duration of rectocele (years)	Awaiting surgery	Current management	
				Use fingers	Other
1	49	0.9	possibly	Yes	
2	37	3	No	Yes	
3	62	2	No	Yes	
4	73	Missing	Missing	No	laxatives
5	69	2	No	No	vibrator
6	54	11	Yes	Yes	enema
7	70	45	No	Yes	
8	54	3	No	Yes	
9	38	6	Yes	Yes	

Analysis of qualitative feedback was undertaken using thematic analysis (Braun and Clarke, 2006). Qualitative data from each questionnaire and the letter were manually extracted, inputted into Word 2010 documents (Microsoft, 2022), and subjected to coding and arranged into themes via tables. Quantitative data are reported descriptively. The evaluation form sought feedback from women on self-

reported effectiveness, ease of use, place of use, convenience (including storage and carrying), and the 'feel' of the device (Appendix 6).

The women offered insightful comments about their usual care (using fingers, laxatives, enemas, or vibrator) as well as using the device, which (for eight of the women) was introduced seven days after recording their usual care (Appendix 17). Managing the problem for many of the women was one of suffering, which they described as backache and feeling of obstruction (Case 1), needing to push (Case 3), unpredictability (case 5), feeling depressed and anxious (Case 6) and a daily struggle (Case 8):

*Loads of backache; had to take laxatives; feels like I have an egg stuck in my vagina (Case 1)*

*Using my fingers has not been effective; feels like I am trying to give birth – have to push so hard – go dizzy (Case 3)*

*Each day was unpredictable with discomfort on several days with bloating (Case 5)*

*It makes me extremely depressed because I am always in pain with spasms; causes me great anxiety and leads to constant diminishing social contact; I have to 'empty' first manually and second using a water/saline enema; makes me tired, lethargic, and depressed (Case 6)*

*Struggle everyday with this condition – ruining my life really; bowel movements with difficulty; having to press on perineum (Case 8)*

Common themes that emerged from all responses about the women's usual care and therefore living with rectal emptying difficulty included:

### **Mechanical problems (pushing/pressing)**

- Feedback demonstrated some of the women struggle with emptying  
*'Needed to push my perineum'* (Case 2) and that their usual care isn't always effective *'Using my fingers has not been effective; feels like I am trying to give birth – have to push so hard – go dizzy'* (Case 3).

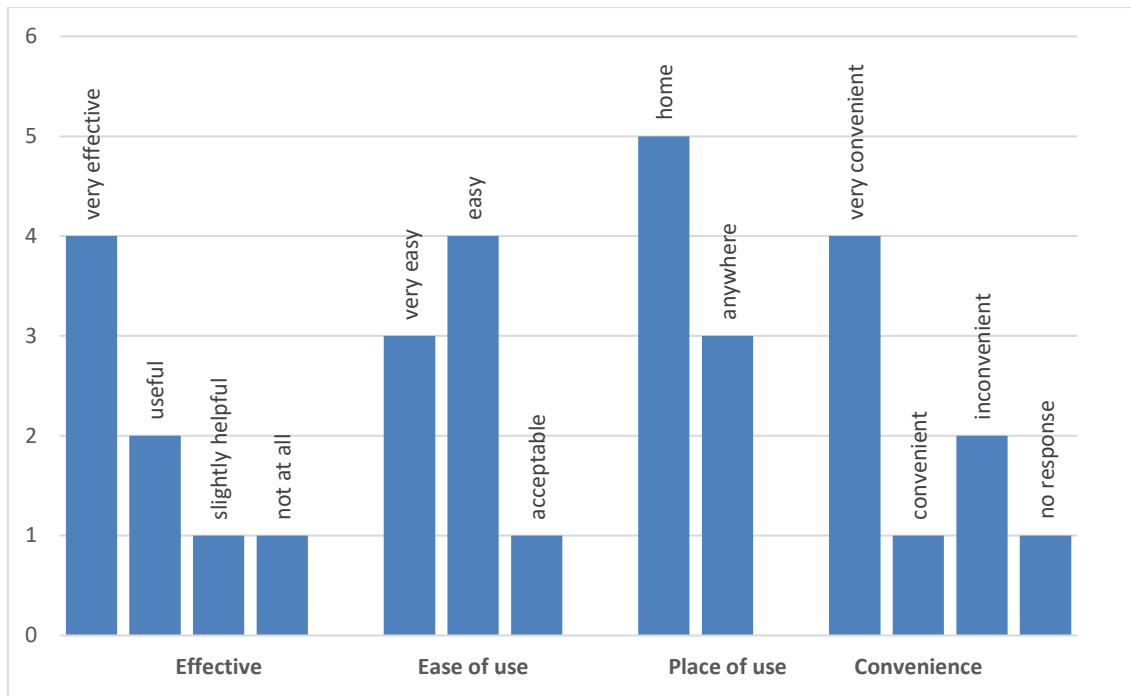
### **Physical effects (backache/bloating)**

- The implications of poor rectal emptying have consequences such as *'Loads of backache', 'had to take laxatives', 'feels like I have an egg stuck in my vagina'* (Case 1). Negative impacts of managing day to day are illustrated by Case 5 *'Each day was unpredictable with discomfort on several days with bloating'*.

### **Psychological issues (anxiety/depression)**

- The accumulation of mechanical problems and physical effects has affected their wellbeing. For example, *'...tried various ideas but nothing was very successful; excessive laxatives every day.....depression set in'* (Case 4). Case 6 commented on *"diminishing social contact"* because being *'in pain with spasms...causes me great anxiety'*.

Within the evaluation form, women also commented on the domains of their experience of self-reported effectiveness, ease of use, place of use, convenience (including storage and carrying), and the 'feel' of the device (Figure 6.1).



**Figure 6.1: Numbers of women reporting on effectiveness, ease of use, place of use, and convenience when using the device**

### *Effectiveness*

Self-reported effectiveness was provided by 50% of the women who responded to this question (n=4). Case 4 was a letter only, and no data were available for effectiveness, ease of use, place of use, or convenience. Four women found the device 'very effective'. The other women responded that it was useful or slightly helpful. Whereas one woman the device was not effective (Case 7):

### *Ease of use*

The device was very easy or easy to use for 89% of women (n=8). One woman (Case 7) advised that using the device is different from using fingers.



### *Place of use*

Five women used the device at home because of ease of access to toilet and washing facilities and the other three used it anywhere they needed to. At the same time, other women felt confident to use it anywhere.

### *Convenience*

Seven women responded to this question with five women finding the device very convenient or convenient to use, mainly because of the velvet-feel black drawstring pouch to store it. Two women found the device to be inconvenient. One of these women who identified the device as inconvenient also reported it very effective (Case 9).

### *'Feel' of the device*

A mixture of responses from the women included it felt "*fine*" or "*ok*". The majority liked the colour of the device and its velvet-feel black drawstring pouch. There was an indication of embarrassment (Case 5), and it met the needs of Case 3.

Case 5 understood the importance of using a lubricant to improve comfort:

Case 8 referred to needing perseverance with using the device. Other suggestions included design changes such as a shorter handle, a smaller carry case and advertising it better so other women could know about it. Adverse events occurred in three cases, abdominal discomfort (Case 2), which settled after her first use. Case 6 reported slight pain and detailed the incremental improvement. For Case 7, the device did not help with emptying the rectum.

### *Preference*

Five out of all nine women (56%) preferred using the patient-centred device compared to their usual care. Three women who did not prefer the device found that their usual care was better for them (Cases 2, 6, and 7). One woman did not reply to this question (Case 9). Table 6.2 shows the range of quotes within the self-reported domains.

**Table 6.2: Quotes from the women within each of the self-reported domains**

Self-reported domains	Quotes
Effectiveness	<p><i>'it has changed my life'</i> (Case 3)  <i>'felt comfortable and gave me more confidence'</i> (Case 5)  <i>'great wee gadget so glad I gave it a try'</i> (Case 8)  <i>'a good product; requires time to use it and takes fractionally longer than a finger'</i> (Case 9)  <i>'not at all effective; felt I did not have the same feeling or control'</i> (Case 7)</p>
Ease of use	<p><i>'brilliant and it is easy to insert'</i> (Case 3)  <i>'not unpleasant but do not get the same feeling as you do when using fingers'</i> (Case 7)</p>
Place of use	<p><i>'work outdoors, no way of carrying it; would prefer my own toilet'</i> (Case 1)  <i>'why struggle so much when the (device) is so effective and so portable – fits in handbag easily'</i> (Case 3)</p>
Convenience	<p><i>'nice handy bag to keep in bathroom – nobody knows what it is'</i> (Case 1)  <i>'the carry case makes it so discreet'</i> (Case 3)  <i>'I keep it...in my handbag'</i> (Case 6)  <i>'but I will keep trying to see if I can get used to it'</i> (Case 7)</p>
Feel of the device	<p><i>'to have somewhere to keep it out of sight'</i> (Case 5)  <i>'everything about it is perfect'</i> (Case 3)  <i>'important to use a lubricant; the case is excellent and a good idea to have somewhere to keep it out of sight'</i> (Case 5)  <i>'Trying something different is always a challenge but the more you use it the easier it becomes – nice feminine colour and wee velvet pouch nice touch'</i> (Case 8)  <i>'slightly painful to use, but need to practice; slightly better on day 2, but did not help evacuate at as much; slight improvement on Day 3; changing diet and eating more fibre; much easier on Day 5; got the knack of using it now, I like it and take it out just in case I might need it'</i> (Case 6)  <i>'I was not sure if I had cleared everything out – so felt uncomfortable; still used fingers'</i> (Case 7)</p>
Preference	<p><i>'No advantage over my usual care; may be more beneficial for women with a more severe rectocele'</i> (Case 2)  <i>'At the moment, I am still more successful in totally emptying when using my finger and enema; Femmeze did push out a lot of unwanted air enabling the stool to be further down the rectum'</i> (Case 6)  <i>'Fingers – I can feel how blocked the bowel is'</i> (Case 7)</p>

Furthermore, the data have been summarised into case stories that helped to illustrate the impact of rectocele on their world, two of which are presented in Figure 6.2.

*Case Report A (Case 3)*

This 62-year-old female has experienced her rectocele for two years and is not awaiting any surgery, because she decided against it. To manage her difficulty with rectal emptying she uses her fingers, but this has not been effective. It feels like trying to give birth and she can feel dizzy by having to push so hard. Using the device has made a significant difference to her life; it enables her to pass her stool easily and without strain. Her preference is to use the device. She has found helpful, easy to use, and convenient to use anywhere she needs to.

*Case Report B (Case 7)*

This 70-year-old female managed her rectocele for 45 years, which had not been suitable for surgery. She uses her gloved fingers, enabling her to empty the rectum easily. The only restriction she experiences with this method is when planning to go out. Using the device did not provide the same relief as using her fingers. After using the device, she still felt uncomfortable (stool in the rectum) and continued to use her fingers. Her preference is to continue using her fingers. She found the device, not at all effective; it was acceptable but inconvenient. She feels only able to use it at home. However, she commented that she would keep using it to get used to it.

**Figure 6.2: Two case reports in the Exploratory Phase**

## **6.5 Summary**

The preliminary insight into the experiences of nine women via self-reported feedback (evaluation form and a letter) suggests positive findings on the impact of the patient-centred device. The results suggest that the device offered most women in this small sample an improved quality of life and a reduction of symptoms they had been living with. Fifty percent (n=4) of women found the patient-centred device effective and 56% preferred it. Whilst this insight did not

provide conclusive results, it helped to unmask the concealed feelings and provided confidence that the research was worthy of continuing. Furthermore, it delivered a stepping-stone to inform Phase 1, a systematic and structured investigation of the rectal emptying problem experienced by women. Chapter 7 details the findings from Phase 1.

## **Chapter 7 Results: Phase 1**

### **7.1 Introduction**

In this chapter analysis of Phase 1 will be presented, generating threads of evidence that contribute to the creation of the tapestry or story. The research question addressed by this phase of the research was:

Does the patient-centred device help women who have rectocele, manage obstructive defaecation more effectively and satisfactorily than their usual methods?

The results are presented and comprise demographic and participant-reported data. The primary outcome measured in this phase was the self-reported effectiveness of the device for participants with difficulty emptying their rectum secondary to obstructive defaecation due to the rectocele. Also included in this chapter are further details related to the PPI between Phases 1 and 2, thereby reflecting the iterative nature of the research.

### **7.2 Aims and Objectives**

The aim of Phase 1 was to identify if this device helps women who have rectal emptying difficulty secondary to obstructive defaecation, manage their symptoms more effectively and satisfactorily than their usual methods.

Objectives:

- Determine the acceptability of the device.
- Demonstrate preliminary self-reported effectiveness of the device (comfort, ease of use, and quality of life).
- Identify any changes to the device or instructions for use (needs adjustment to its design in terms of length/width).

- Determine the ease and willingness of participants to complete questionnaires, and ease of recruitment into a larger study.

### 7.3 Demographic data

#### 7.3.1 Sample characteristics

Thirty-five women between the ages of 24 and 75 years (mean age 52.63 years) participated in the study. All those recruited identified as White British in terms of ethnicity. Body mass index (BMI) ranged from 18.1 to 51.2 with a mean of 29.

Most of the participants have two or more children (Table 7.1). Twenty-two participants (62.8%) out of the 35 reported the presence of urinary incontinence. Two participants advised that they are waiting for bowel-related surgery (7.4%).

**Table 7.1: Number of participants with children**

Number of children	Frequency	Percent
0	3	8.6
1	1	2.9
2	17	48.6
3	11	31.4
4	3	8.6
<b>Total</b>	<b>35</b>	<b>100.0</b>

### 7.4 Participant-reported outcome data

The primary outcome was a self-reported improvement in managing their condition, as determined by completion of the validated ICIQ-VS questionnaire

and the validated Obstructed Defaecation Syndrome Questionnaire. Complete data from pre-and post-intervention for analysis were available from 20 (57%) of the participants. Although all 35 participants provided demographic data and completed baseline questionnaires, missing data was seen with 15 participants. Fully complete post-intervention data were missing for nine of them (Table 7.2). Therefore Table 7.2 sets into context the data completeness. The questionnaires were only partially completed for six participants, leaving some questions blank despite handing back questionnaires. The researcher made several attempts to retrieve these missing data from the 15 participants. Reasons for missing data included questionnaires lost during house moves or mislaid within the home; unsuccessful attempts to contact participants (emails, telephone, and letter); or posted questionnaires were lost in the post.

**Table 7.2: Summary data**

Data collection tool	Number of participants who completed		Complete missing pre-intervention data	Partial missing pre-intervention data	Complete missing post-intervention data	Partial missing post-intervention data
	Pre-intervention	Post-intervention				
Quality of life instrument: ICIQ-Vaginal Symptoms	26	26	9	0	9	0
Obstructed Defaecation Syndrome Questionnaire	33	32	0	0	13	1
Proctogram	27	NA	8	0	NA	NA
Bowel diary	24	24	9	3	9	3
Patient Global Impression of Improvement (PGI-I) scale	NA	24	NA	NA	11	0
Device feedback questionnaire	NA	25	NA	NA	10	3

Participants who responded to the device feedback questionnaire (n=25) reported living with their rectocele for between six months to 40 years, with a mean of 11 years. Twenty-five participants (71.4%) reported on their usual care. Of these,



57% use their fingers to help empty their rectum of the stool as part of their usual care, whereas 14% do not use their fingers to help empty the rectum.

Twenty-seven (77%) of the 35 participants underwent proctogram clinical imaging as part of their usual care pathway. All these participants were subsequently diagnosed as having a rectocele. Seven participants had a proctogram prior to the study. Of the twenty who attended proctogram during the study period, two participants took their device (Appendix 15). Proctogram measurement for one participant showed that the device was positioned correctly but did not evacuate contrast medium. The other participant decided not to use the device at the time of the proctogram measurement. Eight women declined a proctogram because they did not want to proceed, mainly due to embarrassment. Of the 27 participants with rectoceles, 31.4% (n=11) were small rectoceles, 34.3% (n=12) were of moderate size and 11.4% (n=4) were large. Trapping of contrast within the rectum was seen in 23 participants (85.2%); those who did not show this feature had small rectoceles.

The distribution of rectocele size in age groups is illustrated in Table 7.3. Most rectoceles were seen in the 24–55-year age group. Twelve participants were below the age of 50 years.

**Table 7.3: Age and size of the rectocele**

Age	Small	Moderate	Large	Total
24-54	7	5	3	15
55-64	3	3	0	6
65+	1	4	1	6
<b>Total</b>	<b>11</b>	<b>12</b>	<b>4</b>	<b>27</b>

For the 25 participants who self-reported the effectiveness of the patient-centred device, their body mass index (BMI) ranged from 18.10 to 40.80 (mean BMI of 29.09). Table 7.4 shows the distribution of device effectiveness reported by the participants across the BMI ranges. The categories of slightly, useful, and very effective for reporting were combined for the effective column.

**Table 7.4: BMI and self-reported effectiveness of the patient-centred device**

BMI	Not effective	Effective	Total
<19	0	1	1
19-25	1	9	10
26-29	1	7	8
30+	2	4	6
<b>Total</b>	<b>4</b>	<b>21</b>	<b>25</b>

Participants were asked if they had been advised that their condition was suited to a surgical correction, if they were waiting for surgery, had they decided against surgery, and if there had been a previous unsuccessful surgery (Table 7.5). Data were missing from 10 participants, leaving 25 participants who answered most of the questions. Ten (42%) participants were advised that their condition was

suitable for surgery. Of these, three (30%) were waiting for surgery and six (60%) had declined.

**Table 7.5: Participant response for surgery**

<b>Surgery</b>	<b>Yes n;(%)</b>	<b>No n;(%)</b>	<b>Missing</b>
<b>Suitable for surgery</b>	10 (42%)	14 (58%)	1
- <b>Awaiting surgery</b>	3 (30%)		1
- <b>Decided against surgery</b>	6 (60%)		0

### **7.5 ICIQ-Vaginal Symptoms quality of life analysis**

Twenty-six participants (74.2%) completed the ICIQ-Vaginal Symptoms quality of life questionnaire. They answered question 8a 'Do you have to insert a finger into your vagina to help empty your bowels'. The results showed a significant reduction in using fingers to help empty the bowel when using the device ( $z=-2.844$ ,  $p=0.004$ ) with a medium effect size ( $r=0.395$ ). The median score of the need to use fingers decreased from baseline ( $Mdn = 3$ ) to post-intervention ( $Mdn = 1$ ).

### **7.6 Obstructed Defaecation Syndrome analysis**

Twenty-one participants (60%) completed the Obstructed Defaecation Syndrome Questionnaire. The difference in questionnaire sub-scale responses was measured pre- and post-intervention using the Wilcoxon Signed Ranks Test (Table 7.6). The results were significant for five variables. Table 7.6 shows the  $p$  values for the five variables being below the threshold of significance ( $p=0.05$ ); along with the  $z$  value for each, indicating that there is a significant reduction in difficulties to evacuate, digitation to evacuate, the feeling of incomplete

evacuation, straining to evacuate and lifestyle alteration. The effect size was medium across four variables based on Cohen's conventions (Cohen, 1988). Lifestyle alteration showed a small effect.

**Table 7.6: Changes in scores at baseline and post-intervention for the ODS questionnaire using the Wilcoxon Signed-Rank Test**

Variable	p-value	z-value	Effect size
Medication to evacuate	0.102	-1.633	0.25
Difficulties to evacuate	0.004	-2.846	0.44
Digitation to evacuate	0.018	-2.365	0.36
Return to toilet to evacuate	0.464	-0.732	0.11
Feeling of incomplete evacuation	0.002	-3.082	0.47
Straining to evacuate	0.008	-2.636	0.41
Time needed to evacuate	0.559	-0.584	0.09
Lifestyle alteration	0.046	-1.999	0.30

## 7.7 Bowel diary

Twenty-four participants completed a bowel diary pre-and post-intervention. Laxative use did not change pre- and post intervention in terms number of participants using them (Table 7.7). It was statistically insignificant ( $z=-0.414$ ,  $p=0.15$ ) with a small effect size ( $r=0.06$ ) when Wilcoxon Signed Ranks Test was conducted. Two participants' laxative data were missing from their bowel diaries.

**Table 7.7: Use of laxatives**

Laxatives	Pre-intervention	Post-intervention
Does not use laxatives	11	13
Does use laxatives	15	11
<b>Total</b>	<b>26</b>	<b>24</b>

The number of participants who experienced soiling before and after using the patient-centred device showed no difference ( $z=-0.378$ ,  $p=0.71$ ) with a small effect size ( $r=0.05$ ). Stool consistency type pre- and post-intervention did not show statistical significance when exposed to Wilcoxon Signed Rank Test ( $z=-0.163$ ,  $p=0.87$ ) with a small effect size ( $r=0.02$ ). Participants reported their stool consistency to vary between Type 1 and 7 (the complete range of stool types).

The sense of incomplete emptying pre- and post-intervention showed statistical significance when exposed to Wilcoxon Signed Rank Test ( $z=-2.646$ ;  $p=0.008$ ), with a medium effect size ( $r=0.39$ ) (Cohen, 1988) (Table 7.8). The median score of the sense of incomplete emptying decreased from baseline ( $Mdn = 1$ ) to post-intervention ( $Mdn = 0$ ).

**Table 7.8: Sense of incomplete emptying at baseline and post-intervention result using the Wilcoxon Signed-Rank Test**

Incomplete emptying	N	Percentiles		
		25th	50th (Median)	75th
sense of incomplete emptying pre-intervention	23	1.00	1.00	1.00
sense of incomplete emptying post-intervention	23	0.00	0.00	1.00

The feeling of being blocked improved following the use of the device as indicated from changes in the pre- and post-intervention data. Statistical significance was measured using the Wilcoxon Signed Rank Test ( $z=-3.317$ ;  $p=0.001$ ) with a medium to large effect size ( $r=0.48$ ) (Cohen, 1988) (Table 7.9). The median score

for the feeling of being blocked decreased from baseline (*Mdn* = 1) to post-intervention (*Mdn* = 0).

**Table 7.9: Feeling blocked at baseline and post-intervention result using the Wilcoxon Signed-Rank Test**

Feeling blocked	N	Percentiles		
		25th	50th (Median)	75th
feeling blocked at baseline	24	1.00	1.00	1.00
feeling blocked post-intervention	23	0.00	0.00	1.00

## 7.7 Patient Global Impression of Improvement analysis

Twenty-four participants (68.5%) completed the Patient Global Impression of Improvement question post-intervention. Overall, 16 participants (66.7%) reported that the device was better than not using it (the responses for a little better, much better, or very much better are combined) (Table 7.10).

**Table 7.10: Patient Global Impression of Improvement (PGI-I) frequency of response from the participants**

PGI-I	Frequency	Percent
very much better	4	11.4
much better	5	14.3
a little better	7	20
no change	6	17.1
a little worse	1	2.9
very much worse	1	2.9
<b>Total</b>	<b>24</b>	<b>68.6</b>

## 7.8 Patient-centred device feedback

Participants were asked to report on the device's preference, effectiveness, ease of use, place of use and convenience via a device feedback form (Appendix 12).

### 7.8.1 Preference

Twenty-five participants (71.4%) responded to this question within the device feedback questionnaire. When deciding on preference for the patient-centred device or their usual care, 60% of the participants (n=15) prefer the device to their usual care. However, 16% were unsure, with six participants not choosing the device over their usual care. There were missing data from 10 participants.

### 7.8.2 Self-reported effectiveness

On effectiveness, 21 participants (84%) responded. Table 7.11 shows the results of comparing rectocele size as reported via proctogram measurement with the participant responses on the effectiveness of the patient-centred device. Data were available from 19 participants. The remaining 16 did not respond because either because they did not have a proctogram (22.8%) or they did not answer the question on effectiveness (28.5%).

**Table 7.11: Proctogram rectocele size and effectiveness of the patient-centred device**

Rectocele size	not effective	slightly	useful	very
small	1	4	2	1
moderate	2	3	0	4
large	0	0	0	2

### **7.8.3 Ease of use**

The ease of using the patient-centred device was reported by 24 participants (68.6%). Eleven participants advised that the device was very easy to use (45.8%), five participants found it easy (20.8%), and eight found it acceptable (33.3%). One participant responded that the device was difficult to use. There were missing data from 10 participants.

### **7.8.4 Place of use**

Of the 25 participants who responded to the question related to where they chose to use the patient-centred device as part of managing their condition, most used it at home only (n=20, 80%).

### **7.8.5 Convenience**

Participants were asked to report on the convenience of using the patient-centred device, to which 24 responded (68.6%). Nine participants advised that the device was very convenient (37.5%), and seven participants found it convenient (29.2%). Three participants reported that it was inconvenient to use (12.5%), and one reported that the device was very inconvenient. Four participants reported that the device was acceptable (16.7%). There were missing data from 11 participants.

## **7.9 The 'feel' of the device and participant suggestions**

Twenty-four participants reported on the 'feel' of the device (Table 7.12).

Comments about the aesthetics of the patient-centred device were primarily positive.



**Table 7.12: Participants report on the 'feel' of the device**

<b>Participant</b>	<b>Feel of the device</b>
1	very comfortable, clean, sturdy
2	fantastic, wonderful, life so much better
3	slightly wrong shape
4	comfortable
7	comfortable, good packaging
10	if someone saw it, they would not know what it was for
12	feels firm, effective, not comfortable in the hand, never feel the loo is long enough to manoeuvre my arm
13	comfortable inside, smooth, and not cold or hard, pressing is uncomfortable
14	comfortable, carry bag discreet
15	I'm quite tight but once lubricated it went in fine
16	good shape, easy to clean, does what it should
17	feels fine to use
19	comfortable when inside the vagina, not so comfortable for the hand holding it
20	well made, comfortable to use
22	smooth, comfortable
23	definitely helps with evacuation, easy to insert, easy to clean
26	good quality, cold to use, I feel this is more of a last resort device after physio, diet and exercise have been tried or if a person is particularly put off by using their fingers
27	fine
28	once I got used to it all very satisfactory
31	felt odd at first but got used to it
32	felt an acceptable device, the plastic was soft and not cold
33	fairly rigid
34	easy, comfortable
36	I found it smooth but a little large as I am very small

Fourteen participants made suggestions for improvement of the device (Table 7.19). Comments on deficiencies with the patient-centred device mainly focused on the length of the handle and width of the paddle.

## **7.10 Withdrawals**

One participant withdrew from the study within the first week of using the device because it did not help her symptoms.

## **7.11 Patient Participation Involvement (PPI)**

During Phase 1, the first 11 participants were invited to attend a PPI meeting to inform phase 2 of the research, focusing on the feasibility element. Furthermore, it was essential to have PPI to improve recruitment to the study by attempting to identify the potential barriers that may have existed from a potential participant's perspective. Three meetings were held in total, which was held in a local hotel. Consent was obtained to record the discussion using a tabletop voice recorder. The researcher facilitated the meeting, supported by the research information and data officer. The aim was to explore their views about being involved in the research (e.g., completing questionnaires, access to support) and seek their opinion on recruitment opportunities in the next phase of the study. The meeting initially set out to meet PPI principles. However, the experiences shared by the women shifted it into a focus group-type discussion. Although this was not the initial intention, the keenness for the women to share their personal stories was evident, and therefore allowed to flourish.

The group members expressed the extent of the suffering and feeling of isolation that they and other women experience. Support for the study was widespread amongst those who attended the PPI meeting. Women told their stories of living with the problem and shared their experiences of being involved with the research. A richness and honesty emerged, which was unexpected. Their candour was

humbling. The extent to the suffering and feeling of isolation expressed by these women further helped to validate the reason for doing this research.

The learning from this PPI process highlighted the lack of written consent to use the information that emerged in the PPI group meeting, which subsequently did not receive NHSREC/HRA approval to use. Furthermore, challenges included a risk of bias and influence due to the quadruple role (investigator, inventor, clinician, and PPI facilitator). Especially that women would not disclose research weaknesses and scope for improvements. The atmosphere was genial and supportive, helping mitigate the need for intense facilitation. Themes emerged, along with keywords/phrases, and were captured following verbal consent to record the meeting.

Ideas for strengthening the study included more support at being recruited, such as a second face-to-face visit. The conversation revealed concerns and anxieties that had not been previously considered. For instance, fear of using patient-centred devices for the first time for some women. Even though there was verbal tuition on using it, being shown how to use the device was not initially built into the methods. An idea for a patient education video offering a step-by-step guide was welcomed. Furthermore, this would assist women in having an 'introduction to you' section, especially for women who are not familiar with their bodies. The extent of suffering in silence was emphasised by one woman who had not spoken to anyone, and she believed she was the only one with such a problem.

Encouragingly, it was felt that the intervention period of eight weeks was just about right, to allow the early fumbling of using the patient-centred device. As one woman put it, '*...you can write off the first week because it can take that time to get used to it*'. When asked about the questionnaires, most found them easy to complete, yet failed to capture all they had to say. An area for immediate improvement was the questionnaire guidance, which was not explanatory enough from their perspective. A welcome addition for them was the opportunity to speak about their experiences. Therefore, adding in interviews was greeted positively and they felt that recruitment opportunities could be strengthened by using posters within GP surgeries. Enthusiastically they suggested the types of language that could be included on a poster (Appendix 7), initially used within secondary care to encourage women to ask about the project.

## **7.12 Summary**

Chapter 7 has contributed to the creation of the tapestry or story by reporting on the data collected via questionnaires pre-and post-intervention of using a patient-centred device, which used quality-of-life instruments (ICIQ-Vaginal Symptoms and Obstructed Defaecation Syndrome Questionnaires). Most participants used their fingers as part of their usual care to manage the rectal emptying difficulty, some living with a rectocele for up to 40 years. Most women were diagnosed with a small or moderate-sized rectocele via proctogram clinical imaging. Using the device reduced their need to use fingers. Difficulties with rectal evacuation, digitation to evacuate, the feeling of incomplete evacuation, straining to evacuate and lifestyle alteration all improved when the device was used. Laxative use, soiling, and stool consistency were not different before and after using the patient-centred device. However, the sense of incomplete emptying and feeling blocked

improved. The results suggest that the patient-centred device helped participants reduce the need to use their fingers and offered them a better lifestyle. They reported that the patient-centred device was better than not using it, reporting positively on preference, effectiveness, ease of use, and convenience. The PPI group provided valuable information on improving recruitment and progressing the research. Missing data have been reported but not analysed. Additionally, the patient participant involvement and the output informed the study. Chapter 8 reports on Phase 2 of the mixed methods design.

## **Chapter 8 Results from Phase 2**

### **8.1 Introduction**

In this chapter the results of the qualitative phase will be presented, which offers another thread in the weaver's tapestry and sought to answer the following question:

What is the lived experience like for women who experience difficulty emptying their rectum because of obstructive defaecation secondary to rectocele?

Participants who had completed Phase 1 were invited to take part in Phase 2. Firstly, the demographic and interview process are detailed. Secondly, participant experiences living with rectal emptying difficulty because of rectocele is described, and results are presented as descriptive text and tables.

### **8.2 Aims and objectives**

The aim of phase 2 was to understand more fully what the lived experience is like for women with rectal emptying difficulty.

Objectives:

- Learn and understand the experience of women living with the problem.

### **8.3 Description of participants**

Twenty-six participants were interviewed. The age range was 24 to 75 years (mean age 55.42 years). The interview duration ranged between 20 and 60 minutes, and all took place in a location of the participant's choice between September 2015 and November 2018. Participants were identified via secondary care consultants when attending an outpatient clinic appointment and following their recruitment to Phase 1, were subsequently invited to interview.

## **8.4 Interview process and characteristics**

The interviews were for as long as the participant wanted to talk. Although on average, the interview was approximately 30 minutes in length. All but two participants chose an NHS site. These two participants chose a local public house in their hometown at the quiet times to maintain privacy. None chose their own home. Two other participants decided to bring along their partners for support. Silences were a frequent feature, which reflected the times when the participants struggled to articulate their thoughts. For many, the deepening of their thoughts led to tearful episodes. When describing their use of fingers, this tended to be a trigger for their tears. Despite offering to stop the interview and reschedule, none chose to do so and wanted to continue. The fluency of the interviews varied from a flowing discourse to staccato. The latter was with a participant who struggled to find words to describe her situation, other than the practical application of what she was doing daily.

## **8.5 Framework analysis**

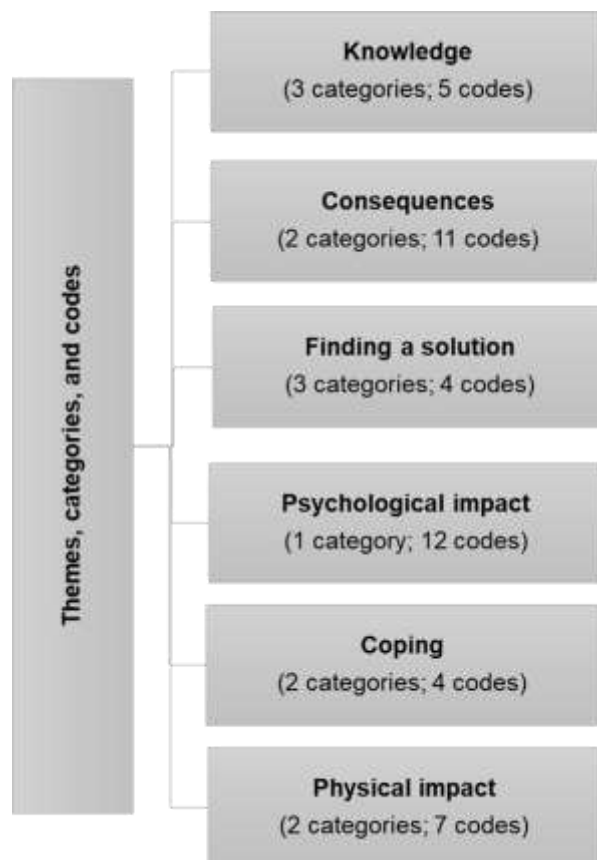
Framework analysis (Gale *et al.*, 2013, Pope *et al.*, 2000) enabled flexibility and an in-depth look into the lives of the women living with rectal emptying difficulty. The seven steps provided a systematic approach to the analysis of the qualitative data and allowed for modification of questioning arising from the emerging themes (Table 5.5 see section 5.9.4). The semi-structured interview schedule aimed to draw out experiences of living with the problem. A priori concerns, supported by themes emerged from the exploratory phase, included:

- Living with the problem (Chapter 6):
  - Mechanical problems
  - Physical effects

- Psychological impact
- Using the patient-centred device
- Being part of the study

## 8.6 Themes from the interview data

Analysis of the interview data (26 participants and one PPI meeting transcription) revealed six themes: knowledge, consequences, finding a solution, psychological impact, coping, and physical impact. The themes emerged from thirteen categories and forty-three codes (Figure 8.1). Figure 8.1 illustrates a theme relationship prompted by the number of aggregated coded references for the theme, devised from the framework matrix (Appendix 18).



**Figure 8.1: Relationship of themes**



## 8.7 Coding agreement

Coding was checked with an independent reviewer for five participants' transcripts. The coding agreement was reviewed using Kappa Coefficient (Wan *et al.*, 2015), applied within NVivo 11. Fair to a good agreement (0.4543) on coding was established and offered confidence with the process. Although considered controversial to use a quantitative measure to qualitative data, maximising the trustworthiness of the coding process adds strength (O'Connor and Joffe, 2020). Any disagreement was resolved by discussion. An example of the coding journey from the framework matrix is seen in Appendix 19.

## 8.8 Theme: Knowledge

The theme of knowledge materialised from the highest number of codes (Table 8.1). Within this theme, three categories emerged: communication and information, metacognitive knowledge, and factual knowledge. Codes that fed the categories resulted from the participant comments.

**Table 8.1: Knowledge theme, category, and code**

Theme	Category	Code
Knowledge	Communication and information	Raising awareness
	Metacognitive knowledge	Knowledge of self
		Perception of self
		Toileting experience
Factual knowledge	Seeking understanding	

### 8.8.1 Communication and information

Participants' comments encapsulated the importance of raising awareness. For example, one participant shared her experience of stumbling across the method of digitation to manage her problem, which made her feel alone because of the lack of information:

*I came across it just by chance that but I could use my thumb I didn't know that's what other people had to do so it would be good if there was more information out there are other people out there that have to do this sort of thing and it just doesn't make you feel like dirty or you're the only one (Participant 29)*

The paucity of verbal or written information, especially within primary care, exacerbated feeling alone and searching for opportunities to talk as portrayed below:

*There's nothing out there talking about this but even if you go into your doctor's surgery you sit down and what do we do you know we said as we scan the walls and were looking and reading whatever information that's up there do you know even if there was a poster sort of saying are you experiencing bowel problems you know this could help it would insight maybe an interest that somebody could actually ask (Participant 10).*

### **8.8.2 Metacognitive knowledge**

Participants identified that self is essential in their experience of living with rectal emptying difficulty. As Participant 21 revealed, knowing more about one's own body was important:

*.....I know the function of it now and what it looks like and I know what goes where and I know how it comes out and now I've got that and I've got that picture and I've got the ways that I squeeze in this way and that way and I take my time it all makes sense and I sort of visualise it a little bit (Participant 21)*

However, perception of one's own body can be challenging to accept for some as participant 21 went on to say:

*...the prolapse was very ugly and horrible when it protruded (Participant 21)*

Early toileting experience influenced beliefs about disgust related to bodily functions as one participant portrayed it:

*..because I thought that bodily fluids and stuff like that it was just disgusting (Participant 36)*

This participant also portrayed bodily function as something that was done in private only:

*if you passed wind in our house it was like oh you had to go to the bathroom to do it (Participant 36)*

### 8.8.3 Factual knowledge

Receiving facts about their condition, for instance during clinical imaging, provided clarity:

*the first time I heard the word digitation was when I had the proctogram and thought oh that's an easier way of understanding it (Participant 22)*

## 8.9 Theme: Consequences

The second dominant theme was consequences (Table 8.2). Two categories emerged, which were the external and internal locus of control. Codes that fed the categories resulted from the participant comments.

**Table 8.2: Consequence theme, category, and code**

Theme	Category	Code
Consequences	External locus of control	Bullying and abuse
		Gender
		Impact of childbirth
		Impact on working
		Aging
		Inconvenience
	Internal locus of control	Intimacy with others
		Lack of control
		Skin health
		Social Isolation
		Time constraint

### 8.9.1 External locus of control

The participants' stories revealed several descriptions relating to an external locus of control. These stories informed various codes of bullying and abuse, gender, the impact of childbirth, impact on working and ageing. These were all factors that led to consequences outside of their control. One interview was particularly harrowing as portrayed by participant 25, who highlighted the graphic nature of bullying and abuse:

*he would go in my vagina up to his elbow I would clamp and it would take an hour for him to or for me to release um and calm down whatever state I'm in I would find that that was some cause of block (Participant 25)*

No other participants revealed abuse of this nature. However, several commented on the gender contrast and how men appear to have a different view of bodily functions:

*men talk about going to the toilet they do don't they, they call it shit, shave and shower so they are quite happy (Participant 13)*

One participant describes how the impact of childbirth can lead to longstanding difficulties with the bowel:

*it's been ongoing really for the past 30 odd years um I suppose I started having problems after my first child who is now 35 and it continued on and off throughout after that (Participant 16)*

The consequence for one participant was profound "I lost my career" (Participant 15). When asked about any worries about living with rectal emptying difficulty, the inconvenience of lack of public toilets was highlighted:

*there are so many public toilets that are closed down that's it's now making it a problem (Participant 8)*

Likewise, the thought of what would happen in the future was a concern:

*I started to think what is going to happen in my extreme old age or I have a stroke or something like that I cannot empty my bowel without assistance (Participant 14)*

### **8.9.2 Internal locus of control**

Several codes reflected participants' influence on their internal control, both positively and negatively. Five codes were assigned to this category: intimacy with others, a lack of control, skin health, social isolation, and time constraint.

Being intimate with another person was a concern for some people as reflected by the comments from one participant:

*I've got on with life fine but I mean I did start a new relationship just over a year ago and that was very very conscious you know I was very frightened of making love in case because I'm very windy with this as well (Participant 23)*

Furthermore, the lack of control of bodily function when out and about appears to take its toll, as described by Participant 8:

*Yeah ooh yeah I mean you know you're walking in on the street you can actually feel it coming out of you, you feel all wet and slimy and oh no not again and you've got not control over it I think that's what it is the control having no control over your own body (Participant 8)*

The size of the rectocele created further problems in that when a rectocele is large, falling outside the vagina and the risk of skin damage. The consequences can be significant:

*they were slightly worried because it was quite large that it would ulcerate (Participant 23)*

Becoming socially isolated was a standard feature, as represented by Participant 36:

*not so willing to go out and about all the time you know spontaneously whereas I would do before but I think that just because it knocks your confidence a bit (Participant 36)*

Participants also expressed issues related to the time constraints of managing rectal emptying:

*then you've got to sit on the toilet then you've got to get your stool out and then you've got to you know assume the right position on the toilet and then you've got to make sure you're breathing properly and all of this is happening and then by the time you have got around to it you think do you know what's the point I can't be bothered now and it honestly just gets you down (Participant 15)*

### 8.10 Theme: Finding a solution

Finding a solution was the third theme (Table 8.3), reinforced by the categories, diagnostics, interventions, and surgery. Like the other themes, codes that fed the categories resulted from the participant comments.

**Table 8.3: Finding a solution theme, category, and code**

Theme	Category	Code
Finding a solution	Diagnostics	Having investigations
	Interventions	Patient-centred device
		Using fingers
	Surgery	Waiting for help

#### 8.10.1 Diagnostics

Participants explained how clinical imaging such as a proctogram was enlightening and formed part of their journey to discovering what is happening to them:

*We did the proctogram and it was like oh my goodness oh my god but it still took a while to find out exactly you know what was wrong but the bowel is very complex (Participant 36)*

However, one participant sourced information on the proctogram from the internet, which was alarming for her:

*And so then I got the information from the internet and it was like a horror story I thought oh that's going to be really embarrassing I didn't know what to expect (Participant 29)*

### **8.10.2 Interventions**

Participants were asked about their use of the patient-centred device in the intervention phase of the study. Participant 12 commented on her reactions to having access to an option for a non-surgical approach:

*Well I was so amazed and that there was something that could be done about this which wasn't an operation because I knew that operation was a horrible one and that was what I was really dreading (Participant 12)*

Alternatively, participants who used their fingers to help empty their rectum sourced how to do this via a friend:

*I happened to mention it to a friend of mine that I work with she was a nurse and she said well just stick your finger in your vagina and push down and it was like a miracle because I had sat there and then I had got addicted to laxatives (Participant 17)*

Or participants navigated their way to this intervention as expressed by Participant 18:

*As I just got older and my muscles had given up I just slowly realised that I couldn't I had to sort of um start to put my fingers up (Participant 18)*

### 8.10.3 Surgery

Waiting for help was, for many, in the shape of surgical intervention. For some, as described by Participant 20, the progression to surgery can take time and be associated with a deterioration in symptoms, with the need to digitate:

*I told the doctor a few times why have I got to and the doctor his very words to me were, he said that there are quite a few people that have to do that, nothing else was said then it wasn't looked into. It wasn't until I had those other symptoms that it was looked into then (Participant 20)*

Alternatively, some surgery was considered a ready solution:

*I thought maybe there's just an operation they can do that and I'll be back to normal but it isn't as simple as that (Participant 29)*

### 8.11 Theme: Psychological impact

The theme of psychological impact identified various emotional factors (Table 8.4).

As before, codes that fed the categories resulted from the participant comments.

**Table 8.4: Psychological impact theme, category, and code**

Theme	Category	Code
Psychological impact	Emotional factors	Embarrassment
		Fear
		Feeling alone
		Feeling angry
		Feeling anxious
		Feeling depressed
		Feeling distressed
		Feeling helpless
		Feeling like a burden
		Frustration
		Self-esteem
Validation		



### 8.11.1 Emotional factors

All participants portrayed several emotions, including embarrassment, fear; feeling alone, angry, anxious, depressed, distressed, helpless, and feeling like a burden, whilst frustration, self-esteem, and validation captured the essence of their emotions. A key barrier to seeking help for many was an embarrassment as reflected by the following comment:

*I was just too embarrassed to go and seek help and I just put up with it (Participant 29)*

Furthermore, fear for what might happen was genuine:

*That maybe umm it could lead to serious bowel problems where umm whatever it is needs to be taken away or can't be repaired I don't know what I'd do with myself I really wouldn't (Participant 22)*

Feeling alone and a minority were prevalent in the comments of the participants:

*And you don't know if anyone else that problem you think well maybe it's just me and then you think you're in the minority (Participant 36)*

However, anger was never far from the surface for some, as Participant 15 expressed:

*Sometimes I would have outburst because I would be really annoyed and I would just say to someone this is what's going on what would you feel if it was you and you do get angry and you do get kind of oh I wish I didn't say that now (Participant 15)*

She went on to describe further her feelings of distress:

*I'm quite a strong character you know and at my weakest moments It has just been what's the point you do wonder not why am I here but it's like why am I getting this punishment.*

Furthermore, Participant 15 voices her sense of helplessness:

*If you keep thinking I can't do this I can't do that your bodies going to say my brains telling me I can't do it so I my brain is right so I won't go to the toilet*

Other emotions such as anxiety and depression intersperse the participants' stories:

*I just thought oh my god I hope that it isn't a big one because you can feel the wetness and especially I used to turn my music up in my room so if I did fart then they wouldn't hear me and you know it was just so I mean the girls in work know I told them they know about it and we just made a joke of it (Participant 23)*

*It's probably made me more depressed because you can't get out of the house (Participant 13)*

Participant 13 continued to say how she felt she was a burden:

*I wasn't able to talk about it freely or discuss it in more detail and because I had had so many things wrong I thought he was probably thinking oh another thing on the list*

In response to a wide range of emotions, participants articulated a sense of frustration:

*Especially when I've had a really big stool in there and it's been difficult to pass I think oh my god this is ridiculous that's the phrases that come to mind this should be happening (Participant 26)*

Participant 12 portrayed recognition that self-esteem is essential in their life journey and having someone to discuss the problem with:

*Because you were the first person I could discuss it with um and it might have been an unlocking of a lot of my lack of self-esteem*

A sense of validation helped to reclaim a sense of self:

*I've got a name and I know that I'm not weird and you know it's not something that has only ever happened to me there are people out there that have the same sort of thing and um there are ways that it can be rectified and ways that it can be*

*managed which is the good thing rather than just sitting there thinking I'm weird (Participant 32)*

## 8.12 Theme: Coping

Tolerance and mastering as essential elements for coping with rectal emptying difficulty (Table 8.5). Codes that fed the categories resulted from the participant comments.

**Table 8.5: Coping theme, category, and code**

Theme	Category	Code
Coping	Tolerance	Being part of life
		Getting on with it
		Secrecy and stiff upper lip - coping
	Mastering	Sharing

### 8.12.1 Tolerance

Participants described their coping mechanisms as having to be tolerant and likened it to being part of life:

*I can't remember for a long long time going to the toilet normally without having to do something (Participant 13)*

Additionally, having to get on with it appeared to be acceptable, especially when compared to other health of life situations:

*Well I just coped with it its part of nature so I have had three kids so I just thought it's just the way it is I mean for goodness sake it's not like being diabetic or something is it or having your leg amputated or living in a refugee camp or anything like that at all you know its inconvenient but it's not I didn't find it majorly traumatic (Participant 27)*

Participants' viewpoints shared a sense of keeping the bowel dysfunction hidden.

Their comments portrayed secrecy and stiff upper lip:

*It wasn't something I was ashamed to do but it wasn't something that I wanted to shout from the rooftops and say this is what I'm having to do (Participant 10)*

### 8.12.2 Mastering

Being able to master changes in their lives brought about by their bowel dysfunction has been positive for some participants, as Participant 21 put it:

*I went back to work she made me write a diary and put things in that I should do you know like do the dishes or Hoover the stairs or shop for your meals or and I broke my whole life down into little bits and put them in a little diary sheet and work back from there and it was brilliant (Participant 21)*

Furthermore, having the courage to share what is happening with those closest to them:

*I felt embarrassed and dirty and I hated it and actually the first person I told was my husband because I found I could tell him anything (Participant 29)*

### 8.13 Theme: Physical impact

This theme exposed the least number of references from participants to a physical impact, in which both internal and external factors emerged from that comment (Table 8.6). Codes that fed the categories resulted from the participant comments.

**Table 8.6: Physical impact theme, category, and code**

Theme	Category	Code
Physical impact	Internal factors	Feeling blocked
		Feeling of something coming out
		Feeling relief
		Pain
		Mechanical impact
	External factors	Hygiene
		Toilets

### 8.13.1 Internal factors

Participant 13 summed up what some participants expressed in terms of what it is like to feel blocked with stool:

*Wake up in the morning completely impacted to the point that it would feel like you know where your anus is it was double the size inside so then no chance in a million years sometimes I would have to put loads of Vaseline on my fingers and put them in and just break it up into pieces (Participant 13)*

The feeling of something coming out was described by Participant 26 as:

*It feels like having another baby*

Feeling relief from evacuating stool from the rectum “*is that ahhh*” as Participant 10 revealed. Some welcomed having diarrhoea to experience a clear-out of stool:

*It was quite a relief to get a bug because it gave me a chance to empty out (Participant 16)*

Having a gut loaded up with stool could be painful:

*My job is an apprentice electrician bending over and stuff was so painful because your belly would be so full (Participant 15)*

Attempts to empty the rectum required using mechanical motion and forces:

*I sort of rock forward and drop back in position and squeezing and sit for anything up to an hour (Participant 8)*

### 8.13.2 External factors

Within this category, hygiene was frequently mentioned by the participants:

*I had the neurosis about the hygiene and making sure that I was clean. That is my biggest worry that is quite big on list that was my biggest worry that I would give myself a horrible disease by touching a door handle and then not sterilising my hands (Participant 17)*

Being able to clean up when needed is not always easy:

*I want to get in a bath and if that's happened at work and its only quarter to ten, I've got another three hours before I can leave the premises (Participant 22)*

Toilet access that can accommodate easy clean-up required the use of disabled facilities:

*I found one of the disabled toilets that's a single cubicle with a sink in it and then I can lock myself in there and I can relax rather than be in a cubicle and hear people coming and going and chatting and things that's doesn't help (Participant 21)*

## **8.14 Summary**

This chapter focused on what the lived experience is like for women with rectal emptying difficulty. Using framework analysis, the findings have been presented from semi-structured interviews with 26 participants who were also part of Phase 1. Data analysis revealed six themes, knowledge, consequences, finding a solution, psychological impact, coping, and physical impact. Interviews revealed the suffering they were experiencing, and many had difficulty in putting what it was like into words. Knowledge was the predominant theme that emerged from the interviews, followed by consequences, finding a solution, psychological impact, coping, and physical impact. Coming into view has been the suffering experienced by participants. The next chapter pulls together the findings into the discussion.

## Chapter 9 Discussion

### 9.1 Introduction

Presented in this chapter will be the discussion and synthesis of the key findings from the two research questions that the thesis set out to answer:

1. Does the patient-centred device help women who have rectocele, manage obstructive defaecation more effectively and satisfactorily than their usual methods?
2. What is the lived experience like for women who experience difficulty emptying their rectum because of obstructive defaecation secondary to rectocele?

The results indicate that women can benefit from the patient-centred device, which offers a self-initiated alternative to digitation for coping with rectal emptying problems. Furthermore, the women in this research have been given a voice, and their lived experiences and suffering, have been disclosed. The exploratory phase (Chapter 6) provided preliminary insight into the experiences of nine women via self-reported feedback (evaluation form and a letter). Whilst this insight did not provide conclusive results, it helped to unmask the concealed world of women living with this problem and provided confidence that the research questions warranted exploration. Results from Phase 1 (Chapter 7) demonstrated that the patient-centred device enabled participants to reduce the use of their fingers to help rectal emptying. Phase 2 (Chapter 8) focused on what the lived experience is like for participants with rectal emptying difficulty. From a weaver's perspective, the weaving of individual threads to make up the whole, and it is this that the chapter offers, a pulling together of the findings. The three phases of this research are brought together, providing depth, and meaning that none of them alone could supply. Thus, this chapter is structured by seeking to understand,

self-management, conservative measures, and medical device development. Furthermore, an alternative to usual care, which integrates the mixed methods findings. Lastly, feasibility will be discussed along with implications on improving healthcare for women with rectal emptying difficulty with focus on the conceptual framework, including methodological limitations. The MMR design facilitated integration, and therefore, interpretation of the findings further enhanced the mixing. A key strength is the pioneering nature of this research. The invention of the patient-centred device was the catalyst to reveal suffering experienced by the participants. The device created a serendipitous opportunity. Just as previous inventors have witnessed (Bennett and Chung, 2001, Gorman, 1995), discovery requires curiosity, flexibility, ability to learn from mistakes, and passion for the subject. Whilst looking to solve a problem in clinical practice, something else useful emerged, that being how these women coped.

## **9.2 Seeking to understand**

Seeking to understand draws upon the exploratory phase of this research. A small cohort of self-selected women who self-purchased the patient-centred device, already on the market, completed the evaluation form contained within the packaging offering feedback on their use of the device. The information provided gave valuable insight into their experiences of coping with the problems of rectocele. The difficulty these women had with defaecation is striking, which most people with normal function take for granted. The tendency for bowel function to be innocuous, implicit, and assumptive is interwoven within the feedback. The literature on stoma formation explores a possible explanation for these findings, which refers to bowel dysfunction destabilising the relationship with the bodily self. For example, Thorpe (2016), in her qualitative study of lived experience with



stoma formation in 12 participants, identified the impact in perception between body and self. Similarity is drawn from the work of Reinwald *et al.* (2018), who make reference to bowel uncertainty, struggle, and preoccupation with the bowel. Thereby, the preliminary insight into these women's experience showcases the unfortunate circumstance that bowel function is rarely discussed (Meyer and Richter, 2015). For instance, only nine of 700 women decided to feedback who had self-purchased the device, suggesting that privacy is vital to them.

Bowel function is mainly a private affair, and for some, it takes courage to raise symptoms with health care professionals, fear and shame possibly lead women finding ways intuitively to manage their problem. Thus, underreporting is not uncommon (Brown *et al.*, 2017). In a cross-section survey study of 172 women attending urogynaecology clinics, Bezerra *et al.* (2014) identified lower quality of life in those with unreported bowel symptoms. They also highlighted the tendency for professionals to fail to enquire about symptoms and for patients not to disclose them. Commonly women find ways to manage their rectal emptying difficulty by using their fingers to add pressure to the perineum or insert them into the vagina or rectum. If this is not effective, the constant feeling of needing to defaecate can lead to numerous toilet visits and thus altered mood. Two women (Case 4 and 6) in the exploratory phase commented on how depression resulted from failed attempts to defaecate easily despite increasing laxative use and implementing a double method (fingers plus enema) to empty the rectum. Therefore, self-management can be defined by these types of behaviours and active participation in problem solving (Corbin and Strauss, 1988).

### 9.3 Self-management

The extremes of self-management interventions that women implement often go unrecognised with a minimal clinical inquiry. Lefevre and Davila (2008) believe similarly, despite focusing predominantly on surgical intervention, suggesting that plainspoken conversations with women are essential. Self-management intervention for rectal emptying difficulty is rarely seen in the literature, as identified by the scoping review in Chapter 3. The scoping review identified only two health care-initiated interventions: biofeedback therapy, and pelvic floor muscle rehabilitation. Even so, authors such as Mustain (2017) are beginning to distinguish between medical management using interventions before the option of surgery. His appreciation of clinical decision-making for either a non-surgical or surgical approach is grounded in having thorough consultations with patients. Furthermore, surgical correction can usually restore anatomy but not necessarily reduce clinical symptoms (Sugrue and Kobak, 2016). This challenge needs to be reconciled before any offer of surgical intervention. Although the literature falls short of tackling how women manage before they present to healthcare, slow progress is being made.

Women using the patient-centred device in the exploratory phase noticed improvement. Furthermore, it highlights that these women reached out independently to seek a solution. Many women can feel alone with their symptoms as reflected through each phase of this research. Restoring normal bowel function is undoubtedly a goal for most people (Hornsey et al., 2018). Hornsey *et al.* (2018) refer to human nature as aspiring to be in excellent health as the 'maximization principle' (page 1). Interestingly they identified cultural holism, or

how the self feels connected to the social network, as a key factor in seeking perfection. In contrast, they suggest a counter-position, a 'moderation principle' (Hornsey et al., 2018 p.2), whereby the individual has less expectation on perfection. In other words, imperfection is just as worthy. Hornsey *et al.* (2018) studied parts of the world (Europe was omitted) that nurtured embedded religion, such as Buddhism or Hinduism. However, the 'moderation principle' concept may help explain why women put up with suffering, especially if they do not feel connected to a social network. Although this research did not explore the social network connections for participants, there is suggestion of what women may tolerate. For example, mechanical, physical, and psychological impact of rectal emptying difficulty in everyday life. However, with the help of this research, women may start to voice their suffering and seek treatment. For instance, despite feeling alone, one woman provides information where she identified that her laxative use decreased after using the patient-centred device, and 'normal functioning' (Case 4) was restored. Likewise, most of the other women in the exploratory phase commented on the positive impact the patient-centred device had made, such as '*it has drastically changed my life*'. The women for whom the patient-centred device was not helpful did not notice an advantage of using the device as opposed to their usual care (Case 2, 6, and 7). Regarding benefit, one comment about the device suggests it being more beneficial for those with a more severe rectocele. Overall, 56% of the women preferred patient-centred devices (five of the nine women).

Self-management decision-making draws attention to underlying assumptions of non-compliance (Paterson *et al.*, 2001). One woman preferred to continue with

using her fingers for rectal emptying, despite the device being helpful. Paterson *et al.* (2001) offer a critical analysis of the non-compliance assumption and suggest that healthcare professionals tend to deem self-management decision-making as successful only if harmonious with healthcare advice and opportunities. More than ever, self-management is considered integral to the NHS strategy of personalised care (Hibbard and Gilbert, 2014). Of course, NHS motivations will draw upon reducing the cost of healthcare but improving patient outcomes. However, effective self-management will require patients to receive problem-solving skills and not just information giving (Bodenheimer *et al.*, 2002). Consequently, respecting women's decision-making is integral to self-efficacy (Bandura, 1977a) if complimented by adequate information and problem-solving skills to avoid compromising patient safety. In summary, self-management is an essential component of a conservative measure approach, although minimal literature exists (Dumoulin, 2016).

#### **9.4 Conservative measures**

Conservative measures need to be exploited, yet sensitively, considering individual preferences (Hicks *et al.*, 2014a). Without opportunity for conservative measures, progression to surgical intervention may escalate. One major issue is the lack of evidence comparing three groups, no intervention, conservative measures and surgery (Aubert *et al.*, 2021). Therefore, consistency in health care delivery may be variable and thus several questions need to be answered that requires further research. Rectocele burden and its consequences are scarcely known (Lefevre and Davila, 2008). As mentioned previously, much of the literature presents surgical approaches to posterior compartment prolapses, of which rectocele is one. So far, there appears to be scope for improving the care

pathway for women at the point of presentation in primary care. Enhancing existing care pathways is an opportunity that can emerge from this research. Delaying surgical intervention or avoiding it should guide assessment and treatment. In a prospective evaluation by Hicks *et al.* (2014a) on 90 women with obstructive defaecation and rectocele treated conservatively, 71.1% improved their symptoms. Whilst the results are encouraging, there needs to be more explicit information available to healthcare professionals and patients of what options are available, underpinned by the best evidence. The scoping review (Chapter 3) revealed two healthcare-initiated interventions (biofeedback therapy, and pelvic floor muscle rehabilitation) but no self-care-initiated interventions. It is not known how many participants in the study (Hicks *et al.*, 2014a) had previously used these interventions. The patient-centred device may have the potential to be added as a self-management intervention into care pathways, which will offer an alternative option for women wanting to avoid or delay surgery. The patient-centred device showed most women who fed back on their experience in the exploratory phase an improved quality of life and a reduction of symptoms they had been living with. Although the sample size was small, the strengths of exploration revealed the lived experiences of women, who provided unsolicited feedback, offering rich detail about their condition and the impact it has on their life. Furthermore, the issues of device design are valuable to consider, such as the convenience of use and in what clinical circumstance would it work best.

## **9.5 Medical device development**

User-centred feedback assists with verification to inform medical device development (Kuhl *et al.*, 2020). Integrating comments from women about their experience of using the patient-centred device is considered valuable (Martin and

Barnett, 2012). Martin and Barnett (2012) acknowledge the complexity of medical device development and encourage user feedback to amplify impact in the clinical world. That said, clinical innovators are often challenged by limited data and inconsistent processes (Krantz *et al.*, 2017). Therefore, when considering the responses from the women about self-reported effectiveness, ease of use, place of use, convenience, storage, and carrying, and the 'feel' of the patient-centred device, their voice needs to be heard so that device development is strengthened. The general overview from women described the device as useful, easy, and convenient; and felt it acceptable to use. Suggestions for design change included the device being made less solid may reflect the degree of rectocele (Case 2) for which it will be most effective; also, the suggestion for the device to be half inch shorter on the handle (Case 5). Case 7 responded that the patient-centred device was not effective and was inconvenient to use. This woman reported that her rectocele has been a problem for 45 years. Maybe due to mastering her technique of using fingers over such an extended period, a new way of managing the problem is not helpful. Unfortunately, participants were not involved at the front end of development for this device. However, their contribution with testing and assessing is critical, which has been recognised through this research.

Likewise, via the device feedback questionnaire in Phase 1, most participants also reported positively on preference, effectiveness, ease of use, and convenience of the device. Furthermore, their comments on the 'feel' of the device were encouraging. Constructive suggestions for improvement included the size and style of the device. Interestingly the variation of participant comments for a smaller, wider, longer, or shorter device reflects the potential need for additional

designs. Seeking the aesthetic perspective of a product is supported by engineering frameworks (Lieberman-Pincu and Bitan, 2021). It facilitates improving the device to reach a wider cohort for self-selected purchase and future investigation. However, it is uncertain from the findings, the views of participants who did not prefer the device or were unsure. Nevertheless, the strength of the participant's feedback correlates with the need for real-world evidence (Resnic and Matheny, 2018). Usefulness of Section 2 and 3 (current management approach and using the device) in the questionnaire was however limited because many participants did not fully complete it. Regardless, the participants interviews drew out the how they were managing and using the device. However, grasping a real clinical problem and seeking to resolve it via non-randomised investigation risks lack of reliability. As explained by Tarricone *et al.* (2016), the proliferation of new medical device developments (outside of drug development) has created an evolving dialogue to respect and accept preliminary research studies that facilitate a better understanding of the device in the clinical setting whilst still adhering to issues of patient safety. Thus, the inclusion of the PPI group was fundamental.

The PPI group provided valuable information on improving recruitment and progressing the research, including device development. The creation of the PPI group within the study was a limitation due to late-onset and inability to provide closure to this group. This arose because participants from the PPI group were not available or not responding to contact after that initial meeting. The challenges of PPI initiation and sustainability are not unknown. Boylan *et al.* (2019) concur with these challenges, for instance, researcher burden to administrate and finance a PPI group. However, the opportunity for PPI is

fundamental and a key expectation of research funders (Domecq *et al.*, 2014).

Whilst the positioning of PPI in this study was deficient, the output was research enriching, insightful, and brought the topic into the spotlight. Similarly, the device captured attention as an alternative option to usual care the device.

## **9.6 An alternative option to usual care**

An alternative option to usual care, using fingers or nothing, the exploratory phase provided a worthwhile insight to help develop the Phase 1 mixed methods design of the patient-centred device in a systematic and structured way. The explanatory element of the mixed methods design was the quantitative phase, which examined the self-reported effectiveness before and after using the patient-centred device for up to eight weeks. All participants used the device up to the duration of the intervention period, and no adverse effects were reported. Followed by the exploratory element, using semi-structured interviews in Phase 2 with 26 participants. The interviews revealed six themes: knowledge, consequences, finding a solution, psychological impact, coping, and physical impact. Particularly how suffering is part of the human condition and illuminates one's ability to cope or not cope. Following analysis of the data from phase 2, linkages between the themes became obvious. Any one theme was not exclusive to another and thus co-dependent in influencing the participants' experience in dealing with rectal emptying difficulty. Hence reflecting the array of thought, feelings, and actions within human nature. How to live well is a cornerstone of philosophy and as Socrates advised, 'An unexamined life is not worth living' (May, 2021 p.109). The findings of this research help to examine the bowel function factor of lived lives. Furthermore, similarities with the theoretical positioning help affirm the meaning, nature, and challenges facing women with rectal emptying difficulty.



The findings identified that most participants used their fingers as part of their usual care for managing the rectal emptying difficulty. For some, living with a rectocele for up to 40 years; and most of them had two or more children.

Consistent with the literature, childbirth is a known risk factor. There is evidence from Dietz *et al.* (2018) who found an association between vaginal parity and development of rectocele in an observational study of 1296 women. In contrast, a more recent study by Dietz *et al.* (2022) identified 27 of 184 (15%) of women who have not given birth had rectocele. Taken together, more needs to be known about the mechanisms causing rectocele.

The chronicity of managing the problem and putting up with it (Bezerra *et al.*, 2014) is likely when symptoms are not severe. When symptoms become severe, women tend to report it (Kim and Kim, 2018). Given the length of time some participants had rectocele (up to 40 years), unsurprisingly, the participants' stories from the interviews exposed the hidden suffering experienced. Resonating with coping behaviour theory (Lazarus and Folkman, 1987), participants highlighted coping by tolerance and mastery of the factors of rectal emptying difficulty. They viewed this as being part of life and having to get on with it, whilst at the same time feeling a strong need to keep it secret. The opportunity for sharing their struggle facilitated mastery, which participants indicated in their coping strategies. Learnings from the coping literature help explain what the participants have experienced (Lazarus, 1993, Lazarus and Folkman, 1987, Roth and Cohen, 1986, Trew, 2011). Women need to discover methods to manage, looking for solutions to make daily life bearable and comfortable. Coping is a concept that we have all

encountered in several situations. These circumstances can include the interplay of emotions, self-awareness, and character strength, and are likely to impact on how each person responds to the stressor.

More rectoceles were seen in the 24-to-54-year age group, of which 12 were under 50 years. This is in contrast to previous studies, where over 50 years of age appears the most prevalent (Aubert *et al.*, 2021, Drutz and Alarab, 2006).

Participants in the BMI range of 19 to 25 reported the device as effective.

However, minimal associations can be observed from this small data, which seems to be keeping with Zenebe's *et al.* (2021) work. They found no evidence of a significant link between BMI and pelvic organ prolapse in a systematic review of 14 publications, subjected to meta-analysis (Zenebe *et al.*, 2021). Though the review did not address symptoms of pelvic organ prolapse, of which rectal emptying difficulty is a symptom secondary to rectocele, it is relevant to reveal inconsistencies in the literature. Most participants were diagnosed with a small or moderate-sized rectocele via proctogram clinical imaging and experienced clinical symptoms. Participants were offered a proctogram as part of their usual care in a secondary care setting. There was sufficient benefit to include proctogram as supplementary data because the information yielded detail on the anatomy. Additionally, to provide feedback on how the device works to reduce faecal trapping. However, the additional sequence to the proctogram measurement did not generate enough data to use within the study. Only two of the 20 participants took their device to the proctogram appointment. This finding may be explained by the participants comments about the proctogram being a worrying and embarrassing investigation. Despite this, for most participants their clinical

symptoms improved with use of the device. However, the presence of a 'radiological' rectocele does not necessarily imply clinical symptoms as in the case for some studies (Dietz *et al.*, 2020 p.1, Dietz *et al.*, 2021). Although, the participants did have radiological or clinically assessed rectocele and clinical symptoms by the nature of the recruitment for this research. Drawing on the participant interviews, their stories suggested the need to find a solution for the clinical symptoms. Participants likened this to having investigations (e.g., proctogram), using the patient-centred device, using their fingers to help empty their rectum, or waiting for surgical intervention. Health-seeking behaviour has been well-studied (Cornally and McCarthy, 2011), and the emergence of internet sources of information is seen as an additional valid tool for problem-solving (Ayers and Kronenfeld, 2007). This may help explain why the patient-centred device has been sought and purchased online. The variety of information sources available is now greater than ever. However, despite the emergence of so many information sources, health-seeking behaviour may be delayed for some, as reflected in the experiences of many of the participants, who believed that they were alone in their suffering. This was further exacerbated by the apparent lack of healthcare professional inquiry on presentation.

The participants' perceptions of knowledge focused on what they know about themselves. Particularly seeking to improve their understanding of rectal emptying difficulty. The work by Helgeson and Zajdel (2017) casts light on patients adjusting to chronic health conditions. However, knowledge is not a factor that emerged in their assessment. Rather, their work focused on resilience, which implies an underpinning element of knowledge with which to build resilience.

Resilience is defined as being ‘...not a personal attribute, nor the teaching of coping skills, but a process of reflection, learning and action focused toward overcoming adversity’ (Kralik *et al.*, 2006 p.199). Furthermore, Kralik *et al.* (2006) argued that that knowledge is imperative as a characteristic for the sense of self. When considering the position of self-efficacy, knowledge is a critical element for determining the ability to manage chronic symptoms (Williams and Rhodes, 2016). However, the consequences of symptoms can be profound. For example, feeling alone and anxious in the context rectal emptying difficulty is not easy to express to friends or family. Although the predominant theme of knowledge was unexpected, it may suggest that bowel mastery is predominately underpinned by a sense of self (Di Plinio *et al.*, 2020).

Many women may not actively seek out information on a symptom due to embarrassment. Therefore, healthcare professional inquiry can provide the lead-in to disclosure. In contrast, a primary care qualitative study that investigated the relationship between emotions and symptoms from the perspective of 15 patients identified that emotional disclosure was spontaneous in consultations (Bekhuis *et al.*, 2020). Furthermore, they found that the relationship between a patient and their emotions presented as separate, connected, or inseparable. Symptom detail for the 15 women in that study, described as musculoskeletal, headache, fatigue, and gastrointestinal, are minimal. However, the findings support the need for HCPs to concentrate on emotions displayed during a consultation, be curious, and actively listen to their patients. Phase 2 interview participants concurred, they voiced their need to be listened to, but few experienced this. Psychological impact disclosed several emotional factors, yet this was fourth in the hierarchy of themes

relationship. The depth of emotion was apparent in the semi-structured interviews, for instance, being tearful and attempting to constrain emotions when telling their story. Emotional regulation has been discussed within the literature, highlighting the importance of well-being and functioning (Koechlin *et al.*, 2018). In their systematic review of 15 studies (Koechlin *et al.*, 2018), maladaptive emotional regulation was a risk factor for developing health gain. Translating the existing evidence into this research context, suggests that those with bowel dysfunction are more likely to experience psychological distress (Rao *et al.*, 2007). Rao *et al.* (2007) prospectively studied 114 patients compared to a control group of 44 patients and identified statistically significant differences in the measures. Those with constipation or difficulty with defaecation were more likely to experience depression, obsessive-compulsiveness, anxiety, hostility, and paranoia. The intimacy of clinical consultations can expose embarrassing and stigmatised issues, such as bowel dysfunction. As HCPs, our challenge is to instil in patients a new sense of confidence in their ability to talk about what they are going through to assist them overcoming a 'spoiled identity' (Millen and Walker, 2001 p.89). A spoiled identity or a perception as not being seen as normal, increases the risk of experiencing stigma, a concept introduced by Goffman (1963). Astoundingly, given that defaecation is a bodily function that every human experience, there continues to be disgust about its discussion and disclosure. As Hwer-Richards and Goodall (2020 p.14) suggest '.....a culture that perpetuates the idea that defaecation is a repulsive, sordid act; individuals receiving care are unknowingly colluding to the shame agenda'. Thus, a drive to reduce stigma has seen several attempts, mainly in the mental health field (National Academies of Sciences and Medicine, 2016) but with varied success.

Statistically significant results from the ICIQ-Vaginal Symptoms (ICIQ-V) and Obstructed Defaecation Syndrome Questionnaires (ODS) identified that the patient-centred device helped participants reduce the need to use their fingers and offered the participants a better lifestyle. Even though having to insert a finger into the vagina to help empty the bowel reduced and emptying improved with using the device, the strength of outcome was moderate (Cohen, 1988).

However, caution must be applied due to the small sample size, as the findings might be a false positive. That said, participants spoke of internal physical factors relating to the difficulty of emptying the rectum and what this felt like. There appears to be little literature that captures what it feels like to push out a stool from the rectum when it is stuck or very large. Silence from both the sufferer and the literature continues to risk hiding the truth. Domenichiello and Ramsden (2019), in their review of chronic pain, suggest that keeping silent can be associated with significant suffering, social isolation, and disability, with an increased burden on healthcare systems. External factors portrayed by the participants stressed the importance of hygiene, for instance, keeping clean and the perception of being dirty. Furthermore, concerns were expressed around the often-limited access to toilets with suitable facilities. Toilet provision in the United Kingdom has been controversial mainly due to changes in Local Authority funding creating a lack of toilet stock and recognising gender-neutral and transgender needs leading to societal discussions on how best to deliver equal access (Greed, 2019, Ramster *et al.*, 2018). Greed's (2019) essay describes the complexity of toilet provision but makes a salient point that regardless of biology or social needs, we all need access to a toilet, handwashing facilities, and privacy.

The ODS questionnaire identified another important finding: improvements with five of the eight variables answered by the participants were seen. When applying effect size to the five improved variables, four suggest a moderate relationship, whereas lifestyle alternation was weak. Even so, participants voiced the consequences of living with rectal emptying difficulty, from the perspective of an internal and external locus of control. Locus of control is linked to social learning theory (Bandura, 1977b), which suggests that an individual assumes learning from events around them, which subsequently influences their behaviour (Galvin *et al.*, 2018). In the context of the research participants, their external locus of control were outside factors that they could not control, for instance, their gender, impact of childbirth, and aging. In contrast, their internal locus of control was perceived as factors that were possible to control, but they could not, such as social isolation. Being socially isolated was something that most felt impossible to change, because of emotional factors around feeling of lack of control with their bowel, or not being able to get to the toilet in time when away from their home. Galvin *et al.* (2018) articulate the motivational components necessary for influencing the outcome, such as positive empowerment, self-efficacy, and coping strategies. The requirement to understand a patient's preferred locus of control can be applied to clinical practice. For example, a patient with internal control may choose to seek more understanding, whereas those with external control may choose to delegate decision-making to a HCP (Marton *et al.*, 2021). Therefore, the HCP should understand how patients present as active or passive participants in clinical consultation. The remaining three variables of the ODS questionnaire, such as medication, return to the toilet to evacuate and time needed had not

exposed any differences. It is unclear why the need to return to the toilet to evacuate did not change. However, it is not surprising that the time needed to use fingers or the device was similar, any additional factor to normal rectal emptying will add time. What is not known from this study is how much time it takes for each self-management intervention.

The findings are consistent with the work of Brown and Grimes (2016), who stress the need for a better understanding of defaecatory dysfunction (or rectal emptying difficulty) and those additional efforts need to be made in this field. In support of this claim, Hicks *et al.* (2014b) make a case for medical management initially for rectocele, rather than resorting to surgery. Unfortunately, there is a dilemma with clearly identifying and clarifying differences between the structural changes causing a rectocele and symptoms experienced by the woman (Sugrue and Kobak, 2016). Therefore, premature surgery is a risk. The option of surgery was offered to ten of the participants, most of whom declined progression to surgery. It is not known why these participants declined. This outcome could be explained by the literature, which suggests that surgery for a rectocele can be complicated and does not always result in symptom relief (Podzemny *et al.*, 2015).

Furthermore, the surgical technique is varied and the detail on which is superior is not clear (Wei-Cheng Liu Song-Lin Wan, 2016). The NICE Clinical Knowledge Summaries on Constipation (NICE, 2021), provides a platform to embed clinical inquiry and self-management intervention options into clinical practise.

The bowel diary completed by the participants provided real-time data before and after using the patient-centred device. Although the findings did not identify any



difference with laxative use, soiling, and stool consistency, the intervention period may not have been enough time to see any differences. Eight participants stopped the intervention before eight weeks, primarily because of life events preventing them from continuing, such as moving to a new house or unrelated ill-health. Thus, this highlights the risk of the small study, which restricts the identification of differences (Hackshaw, 2008). The bowel diary also provided additional data, such as the sense of incomplete emptying and feeling blocked, which improved with the use of the device. Participants were asked to complete the PGI-I scale (Srikrishna *et al.*, 2010) only once, at the end of the intervention period. This research found that most participants (n=16) consider the patient-centred device better than not using it. Although mainstream use of the PGI-I scale is usually in the post-surgery population and not with medical device development, this scale within the research offers a quality indicator. In addition to showing patient-centred device acceptability for participants and uncovering their lived experience, these findings may help us acknowledge the necessity of HCP consultation skills, but the cultural shift in society is needed sooner. Faecal transplantation (Mohammadi, 2016) for a variety of health conditions, mainly infection, is growing in popularity within the medical establishment. Perhaps this, along with reframing human faeces as a universal need for dignity will shape the future (Erridge, 2011). Although challenging, it is time for a renewed visibility of the fabric of human bodily function.

## **9.7 Feasibility**

The objective of feasibility within this research was to assess the intervention process to facilitate progression into further study. There was alignment with feasibility standards, but with a light touch given the iterative and pragmatic

journey. The nature of the work required flexibility and yet recognised its interchangeability with a non-randomised pilot approach (Lancaster and Thabane, 2019). Feasibility is grounded in the intervention process, and the pilot approach is considered a smaller version of a more extensive study (Gadke *et al.*, 2021). Avoiding confusion is critical to ensure that the correct considerations are made. Lancaster and Thabane (2019) agree and emphasise the importance of transparent reporting to enable replication of the study. Although they are advocates of the CONSORT protocol (Eldridge *et al.*, 2016), which facilitates quality assessment, there is another template specifically for interventions. The template for intervention description and replication (TIDieR) checklist and guide (Hoffmann *et al.*, 2014) provides an opportunity to improve reporting and give clarity to the complexity of this study (Table 9.1). In the spirit of the recommendation from Hoffman *et al.*, Table 9.1 describe this study's items and an explanation alongside the checklist elements.

**Table 9.1: The TIDieR (Template for Intervention Description and Replication) Checklist (Hoffmann *et al.*, 2014)**

<b>Checklist</b>	<b>Item</b>	<b>Explanation</b>
<b>Name</b>	Patient-centred device	
<b>Why</b>	Provide an alternative intervention to help women who have rectocele, manage obstructive defaecation more effectively and satisfactorily than their usual methods.	Scoping review of available interventions reveal a lack of self-management interventions.
<b>What</b>	Thirty-five female participants were given a patient-centred device to use for up to eight weeks instead of their usual care for rectal emptying difficulty.	Differences in usual care and using the patient-centred device were measured with questionnaires before and after. All participants were invited for proctogram clinical imaging as part of their usual healthcare journey.
<b>Who provided</b>	The intervention provider in Phase 1 was the inventor of the device, the principal investigator of the study, and the clinician. The provider also interviewed the participants in Phase 2.	Co-investigators in the study were medical consultants within secondary care who facilitated the selection of the participants if they met the inclusion criteria. Proctogram clinical imaging was provided within the same secondary care hospital.
<b>How</b>	The researcher (provider) contacted interested participants to consent and recruit them to the study. Contact was made by telephone or email within two weeks of starting the pre-intervention (completing questionnaires at baseline).	Participants were seen face to face for their interview (Phase 2) following completion of the intervention (Phase 1).
<b>Where</b>	Participants were identified from secondary care gynaecology or colorectal clinics within an English county.	For the interviews, participants chose the location to be seen.
<b>When and how much</b>	During the intervention period of up to eight weeks, participants had open access to the researcher by telephone or email, tailoring to any specific needs	

<b>Tailoring</b>	All participants received the patient-centred device, which was box packaged with a drawstring pouch, introductory lubricating gel, and written instructions provided free of charge from the manufacturer.	Participants were asked to alert the researcher of any concerns with using the device (e.g., pain). Reporting of all adverse events to MHRA and the manufacturer.
<b>Modifications</b>	Slow recruitment delayed the study duration.	With PPI recommendation and support, recruitment posters were introduced into secondary care.
<b>How well</b>	Adherence to questionnaire completion by participants was variable.	Correspondence and telephone/email contact with participants failed to retrieve all questionnaires.

The checklist helps reassure and provide confidence in systematic reporting.

However, the checklist does not clarify how and where to report on feasibility.

Similar to the findings of Van Vliet *et al.* (2016), who identified shortcomings in their practical application of the checklist for functional strength training, the checklist is worthy for standardising the description of an intervention.

Addressing feasibility is imperative, and in this instance, aligns with Eldh *et al.*'s (2017) work, which highlighted the importance of such activities, especially where the research journey is challenged by a lack of evidence base for clinical intervention and where evidence for implementation is weak (Figure 2.4). Whilst this research has taken a light touch to feasibility robustness, it does inform future investigation (Gadke *et al.*, 2021). Gadke *et al.* (2021) explain how best to involve feasibility procedures in the research, aiming to illuminate how possible it is to do something. Feasibility questions developed after their feasibility trial within psychology and education, offer a scaffold to check what modifications may be necessary for this research (Table 9.2). This question set has been used to identify modifications needed to address patient and public involvement (PPI),

education associated with the patient-centred device, improving recruitment, and managing the questionnaire procedure to reduce missing data.

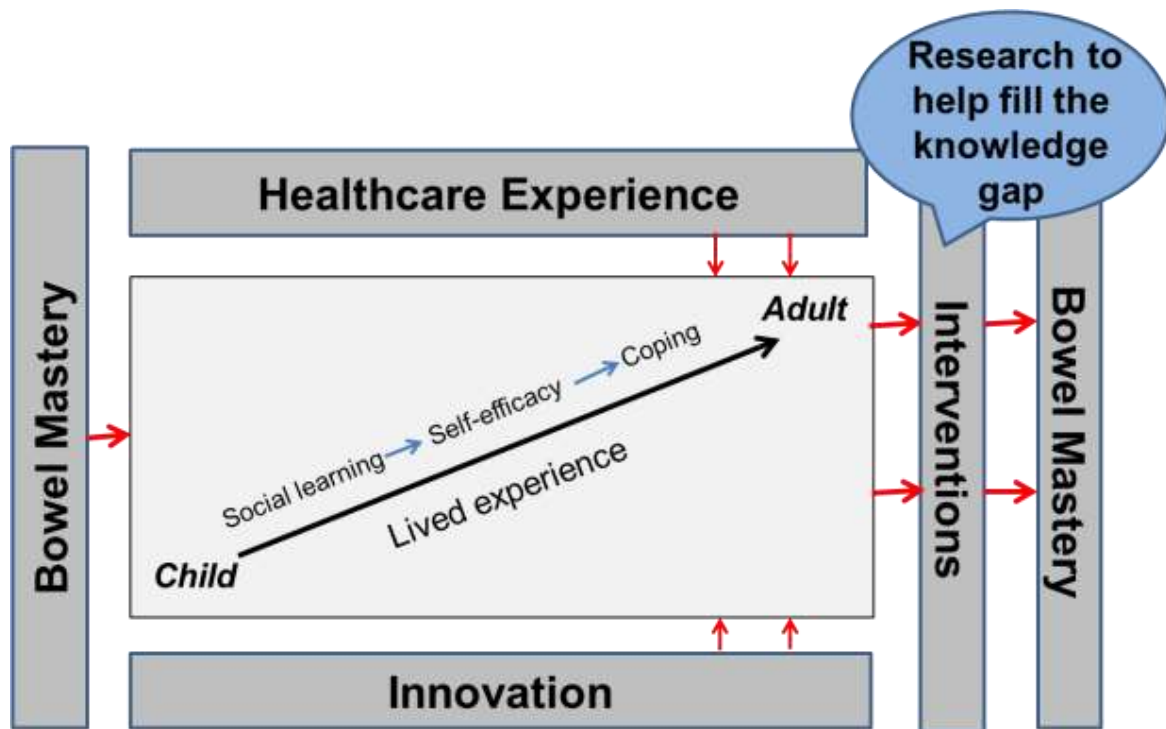
**Table 9.2: Feasibility modifications (Gadke *et al.*, 2021)**

<b>Feasibility dimensions for assessment</b>	<b>Specific questions to be addressed</b>	<b>Measures to address the questions</b>	<b>Decisions to consider for progression to a larger study</b>
<b>Recruitment capability</b>	Can participants be recruited to the study?	Face to face introduction to the study within secondary care outpatient clinics; recruitment poster in specific outpatient departments; recruitment was slow.	Multi-site recruitment.
<b>Data collection procedures</b>	Are the current measures adequate to collect data?	Use of validated and bespoke questionnaires; descriptive and patient-reported data analysis.	Obstructive Defaecation Questionnaire was too difficult for some participants to complete; a review of the questionnaires was necessary.
<b>Design procedures</b>	Is the pre- and post-intervention period optimal?	Discussions with research experts; mixed-method design deemed most suitable; eight participants completed within less than eight weeks.	A more extended intervention period may improve results.
<b>Acceptability</b>	Have participants been involved in the study design?	Late introduction of PPI within Phase 1.	Establish the PPI group at the planning stage and maintain it throughout the study.
<b>Practicality</b>	Does the study design support implementation?	Explanatory sequential design (QUAN→QUAL) preceded by an exploratory phase.	Mixed methods are considered appropriate to answer the research questions.
<b>Integration into an existing system</b>	Will the study findings enable the embedding of a new device into current healthcare?	The exploratory phase revealed that women self-select the device outside of formal research.	A larger study will provide the device with increased traction to dovetail into existing clinical care pathways.
<b>Implementation</b>	Did participants implement the device as intended?	Verbal and written instruction for the patient-centred device at the	Participant feedback advised investing more time for education on the use

		beginning of the intervention.	of the device and offering face to face tuition.
<b>Effectiveness</b>	Does intervention data show promise for the effectiveness of the device?	Pre- and post-intervention data collection.	ICIQ-vaginal symptoms quality of life analysis: a statistically significant reduction in the need to use fingers to help empty the bowel when using the device ( $p = 0.004$ ); obstructed defaecation syndrome analysis: a statistically significant improvement in overall scores when using the device ( $p = 0.046$ ).

## 9.8 Conceptual Framework

As new knowledge emerges, this needs to be synthesised and interpreted to clarify how this learning can be used in clinical practice. Thus, helping women to self-manage the chronic condition of rectal emptying difficulty. A preliminary conceptual framework's development helped to illustrate this contribution to knowledge as reported in Chapter 4 (Figure 9.1).



**Figure 9.1: Bowel Mastery Conceptual Framework**

Building the preliminary conceptual framework from the ground up can be complicated and intimidating. While there is a growing consensus on achieving this (Green, 2014, Miles and Huberman, 1994, Maxwell, 2013), the researcher must think deeply and make decisions about what is vital for their research. The researcher needed to be mindful that the conceptual framework is to justify and describe what the study is about. In contrast, a theoretical framework reflects what work or theories are driving the research (Varpio *et al.*, 2020). Therefore, developing the preliminary conceptual framework provided an illustrative, woven representation of the concepts that had emerged from the previous chapters (Chapters 1, 2, 3, and 4), primarily from the theoretical positioning, scoping review, and researcher experience. Moreover, it clarified why this research was necessary, and what contributions its findings and synthesis will make to the lives of women who experience rectal emptying difficulty. Subsequently, following the



analysis of the results from the exploratory phase, Phase 1 and 2, in the spirit of MMR, the conceptual framework was modified to provide unity and coherence. A second iteration of the conceptual framework (Figure 9.2) takes a further step showing a three-tiered illustration of the lived experience for women along their journey of rectal emptying difficulty. The three tiers focus on mastering the bowel, healthcare experience, and interventions. The usefulness of the conceptual framework is enhanced by including what interventions can be offered at each step of a woman's experience. The patient-centred device is positioned at the 'accessing care' step.

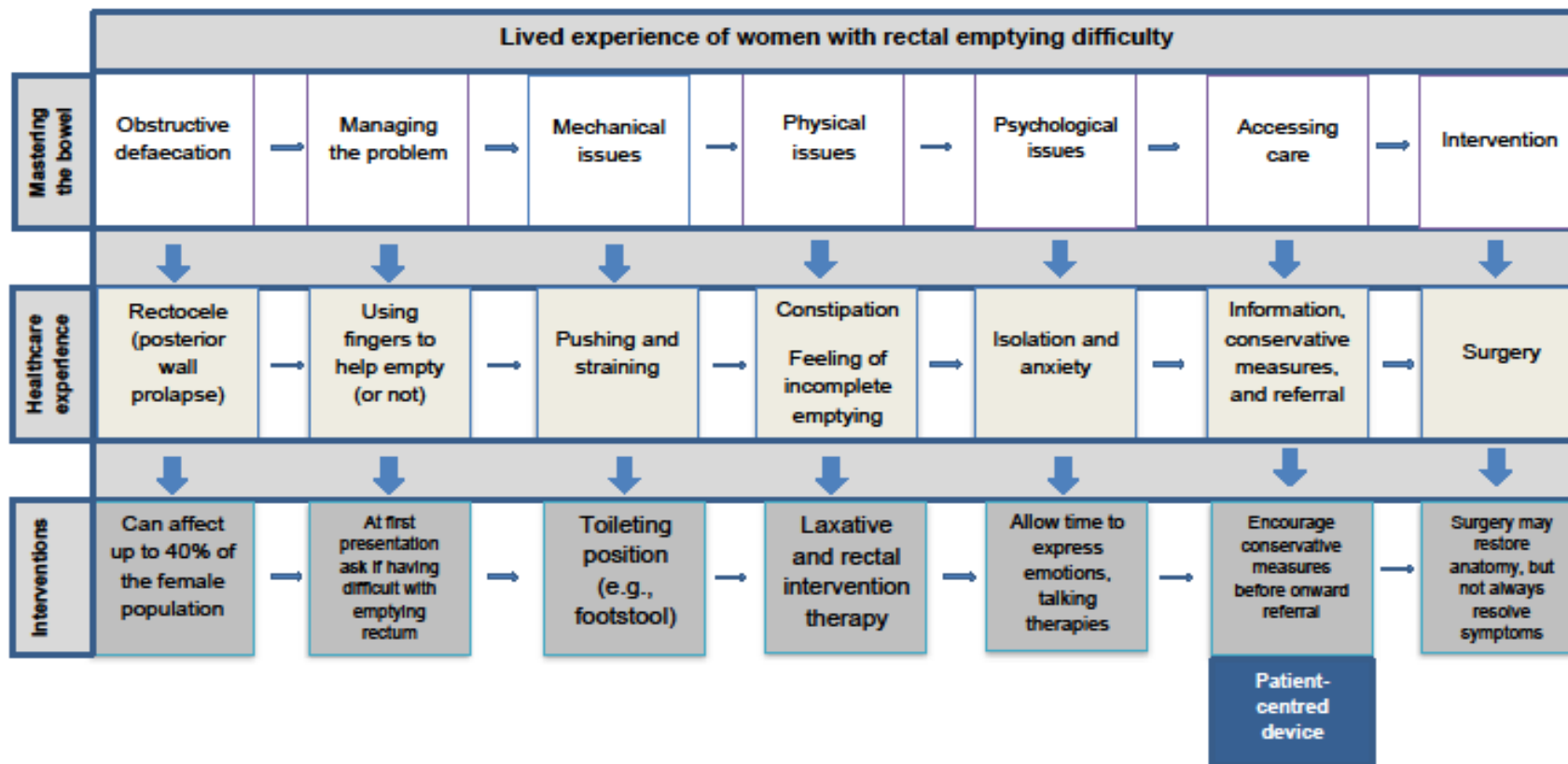


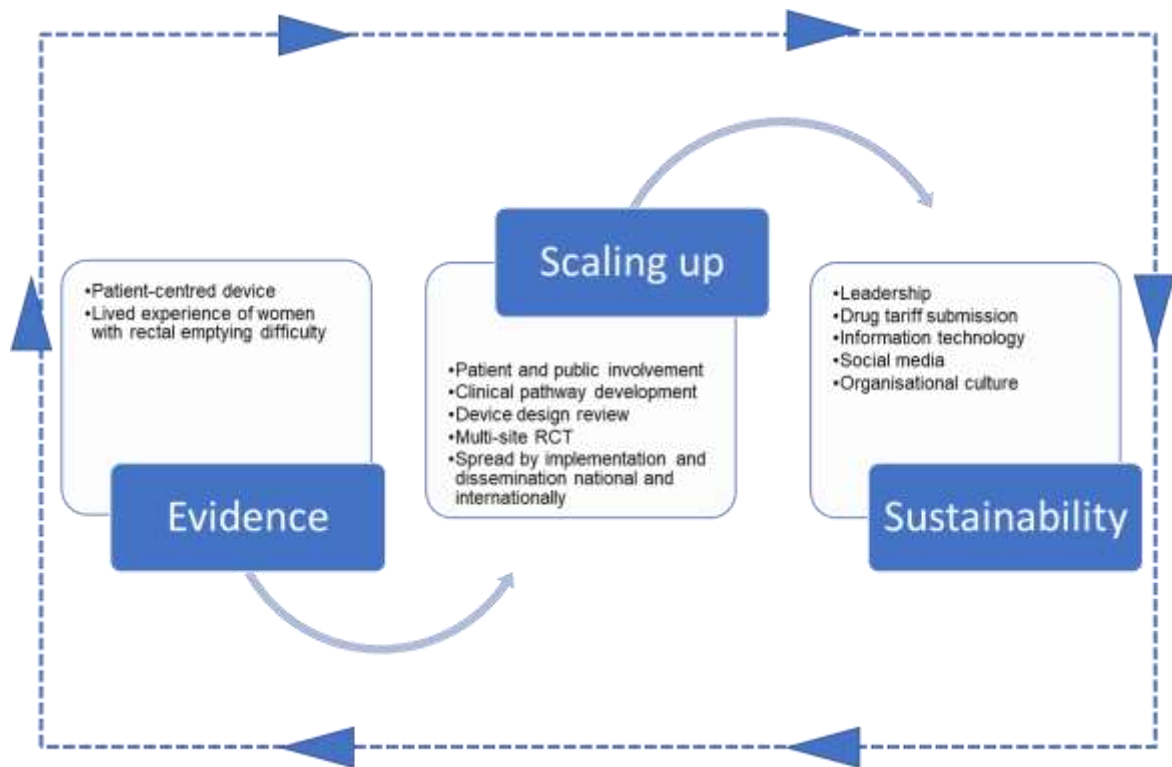
Figure 9.2: Bowel Mastery Conceptual Framework - Lived Experience

Although this conceptual framework iteration is helpful, it does not address the organisational and leadership factors that foster scaling up and sustainability (Sarma *et al.*, 2021). Furthermore, it is critical to acknowledge that the research to narrow the knowledge gap was only partially accomplished, in part due to the small sample size for all areas of the study. Any future investigation will provide an opportunity to enhance understanding and clarity further.

### **9.8.1 Applying the framework to inform healthcare delivery**

The Bowel Mastery conceptual frameworks (Figure 9.1 and 9.2) offer vision and insight into what the lived experience can be like for a woman experiencing rectal emptying difficulty. This is a life-long journey, stretching from learning about bowel control in childhood through adulthood. Although the complexity of the inter-relatedness can be observed in the framework, it is not an exhaustive explanation due to the nuances of human nature. The work of McDonald *et al.* (2007) can be drawn upon to inform this work further. They critically analysed several quality improvement strategies and suggest how conceptual frameworks can assist with the transference of knowledge into better care coordination. Of the four frameworks they studied, the organisational design framework identifies the uncertainty and complexity of successfully translating care into improved health outcomes. Drawn from the work of Wagner's Chronic Care Model (Wagner *et al.*, 2001), the model postulates that without the alignment of the proactive patient, in conjunction with proactive health care, better health outcomes may not prevail. Advancing this idea, Boehmer *et al.* (2018), in their systematic review of people living with multi-morbidities, contribute a patient-centred position, whereby

intervention is dynamic and should be cognisant of the patient experience. Another example is Sarma *et al.* (2021), who applied a conceptual framework using an implementation science approach for nutritional intervention in their narrative review. They suggest a conceptual framework that includes the elements of efficacy, scaling up, and sustainability, which is a practical application for the real world. With the work of Sarma *et al.* (2021) in mind, an implementation framework evolved as a third iteration, which has fostered all elements necessary for improved benefit and meaningfulness to healthcare (Figure 9.3).



**Figure 9.3: Implementation framework for rectal emptying difficulty in women (Sarma *et al.*, 2021)**

### 9.8.2 Benefits and limitations of the framework

The conceptual framework was developed from the theoretical positioning for the research, the scoping review, and the experiential learning and knowledge of the

researcher (whilst also being the inventor and a clinician). The modelling of the inter-connectedness of the relationships has facilitated the course of the work. Yet one main limitation is the lack of evaluation and how impactful the conceptual framework will be in healthcare practice and organisations (Table 9.3). That said, facilitation towards Drug Tariff admission can be strengthened, meaning that the patient-centred device can be available via prescription. The Drug Tariff is a monthly paper or electronic publication produced by the NHS Prescription Services on behalf of the Department of Health and Social Care (NHS Business Services Authority, 2022b). Application to the Drug Tariff is via a formal process, and it is anticipated that the patient-centred device will be available for use through the DT1 Form Part B (CE Marked Class I Non-Sterile Medical Devices) (NHS Business Services Authority, 2022a).

**Table 9.3: Benefits and limitations of the Bowel Mastery Conceptual Framework**

Benefits	Limitations
Captures the relationships between the theoretical positions, the scoping review, and researcher knowledge, which has been missing from the literature.	Theory choice only focused on a psychological lens.
Included concept portrays a linear journey from child to adulthood of mastering bowel control.	No single defining concept has emerged.
Offers representation of the lived experience of women with rectal emptying difficulty.	Leadership and implementing the framework into everyday healthcare practice are not explicit.
Facilitated development of the research questions.	

## 9.9 Limitations of the research

Several limitations exist throughout the research, which needs to be acknowledged. Although some limitations have been raised during the discussion, this section focuses on key areas that enrich and facilitate further research on this topic. Key areas include bias, lack of previous research studies, time constraints, sample size and recruitment, data collection by questionnaire and interview, interpretation of results and loss of contact with the PPI group.

### 9.9.1 Bias

Faith in the scientific rigour of research is fundamental (Pannucci and Wilkins, 2010). Although bias can occur at any point during a study, outlining the limitation provides transparency. The researcher was involved in recruiting of participants, data collecting and analysis, and providing therapeutic guidance during the

intervention period, in addition to being the device's inventor. All of this necessitates caution. Helping to mitigate the limitation included sense-check meetings with members of the supervisory team and an independent assessor to discuss steps of the research study. Additionally, reflective practice at peer support meetings and notetaking facilitated insight.

### **9.9.2 Lack of previous research studies**

Given the pioneering aspect of the research study on a patient-centred device for rectal emptying difficulty, there was limited available evidence on which to draw from. While this is a drawback, it also provides a chance to identify a knowledge gap, contribute to narrowing the gap and describe the need for additional research (Tarricone *et al.*, 2016).

### **9.9.3 Time constraints**

Phase 2 interviews were conducted over three years, influenced by researcher clinical workload, access to participants and slow recruitment. Whilst research delay reasons are commented on within the literature, little attention is given to the clinical context (van de Schoot *et al.*, 2013). Ways to manage this included timetabling, day-to-day management of diary commitments, but recognition of what is controllable. For instance, delay in recruitment was not controllable, but clinical workload was to a certain extent, with flexibility and team support.

### **9.9.4 Issues with sample size and recruitment**

The small exploratory phase sample size made it difficult to draw any firm conclusions. Although the findings help provide a baseline, they are not conclusive, at least not until replicated. Furthermore, the data do not include those women who did not like the device or found it ineffective since they appear

to have been less likely to have completed the evaluation form. There is also the reliance on women self-reporting rectocele when they may not have had this condition, which may lead to an over or under estimation of their symptoms. Nevertheless, the sample was spontaneous and offered a unique insight into women who found their way to this device and decided to use it. The evaluation form was purposely developed to uniquely explore the device, and refined following user feedback, was not systematically tested before use. Despite these clear limitations, it was a starting point. It helped inform the mixed methods design for Phases 1 and 2, which allowed further investigation into an incomplete picture of the lived experience of women who resort to using digitation to help with rectal emptying.

Recruitment for Phase 1 was slower than expected. The number of women accessing secondary care was anticipated to be frequent enough to meet the sample of 34 participants within three to six months. Based on local data, between 2012 and 2014, 117 posterior repair procedures within the local secondary care setting were performed (personal communication). Given that not all outpatient consultations will convert to surgery, there was confidence that recruitment would have been on target. There were difficulties accessing reliable data to inform recruitment expectations because of challenges with locating the right team and gaining permission to access the data. Keeping the research site and the relevant co-investigators up to date with the study progress helped maintain slow but steady recruitment. For example, not all of those approached wanted to take part. The secondary care consultants, who screened the women and alerted the researcher to contact them, identified three women who had



changed their minds. One of them decided she did not want to proceed to the consent stage due to her busy working life. The other two women did not feel ready to participate because of other co-morbidities consuming their attention. Despite the participants having rectal emptying difficulty in common, not all participants were comparable due to several variations noted with the demographics and clinical presentations of the women invited to participate in this research. For example, women recruited to this phase may not have previously exploited a range of conservative measures to help their symptoms. This was a missed opportunity in the data collection. Therefore, when recruited to the study, women were at different stages of their journey, and referral bias was a risk (Logroscino *et al.*, 2018). For instance, primary care referral practices will vary in decision-making thresholds, that is, at what point to refer a woman onwards. Whilst acknowledging this variation and that participants may be different to those who did not reach secondary care to access this research, it was not controlled for, the pragmatic approach is necessary for a subject that is hidden and largely secret.

#### **9.9.5 Data collection by questionnaire**

The modified Obstructed Defaecation Syndrome Questionnaire (ODSQ) (Longo, 2003) was not straightforward to complete and the instructions were not sufficient to enable all participants to self-complete. Interpretation of some questions (e.g., medication to evacuate) was ambiguous. Participants could interpret this as taking an oral laxative or using a rectal suppository. With the enrolment of the first participant, the ambiguity became apparent, and so was helped to complete the questionnaire at pre-intervention. This approach was taken with the other

participants to reduce inconsistency and error. An unintended consequence is the researcher influence on the participant answering that question. Completing the questionnaires was prone to error, with some participants failing to complete the post-intervention ODSQ, which further highlighted concern about the ease of understanding the questionnaire. Completion rates did increase with reminders from the researcher. Therefore, missing data remained an issue. A subsequent controlled study will need to consider concerns surrounding the ODSQ and decide if an alternative validated questionnaire is more suitable.

The return of the composite questionnaire and device feedback questionnaire at the end of the intervention period was inconsistent. Despite having completed them, four participants did not return them (forgotten; “*need to dig them out*”, too busy to post). Stamped addressed envelopes did not yield a better return. Therefore, alternatives to postal questionnaires may improve the response rate in a subsequent study. As reported in the literature on questionnaire design, response rates are notoriously challenging (Rowley, 2014, Lee and Lings, 2008). Retrieving the questionnaires following completion by the participants identifies challenges. Gentle prompting by telephone revealed busy lifestyles or being unwell. The promise of getting them returned was frequently given, but this did not always happen. It is essential to be mindful that frequent gentle persuasion could be seen as coercion. Consequently, missing data were common and complete data for pre-and post-intervention analysis were available from only 20 participants. Furthermore, the device feedback questionnaire was unvalidated, although not uncommon in patient-reported outcomes (van der Meulen *et al.*, 2021), the need for standardisation will be necessary for future research.

### **9.9.6 Data collection by interview**

Phase 2 was dependent on disclosing personal experiences from the participants within the interviews. The dilemma of the reluctant participant shone a light on and led to reflection about the researcher's interviewing style (Adler and Adler, 2003). The participants' hesitancy underpins the reluctance in this context to articulate their personal stories. The style of questioning, noticed upon listening to the first eight transcripts, lacked mirroring of the participants' own words and missed reaching the depth of their experiences. Whenever some participants were reticent to talk, there was a tendency for the researcher to attempt to fill in the gaps to avoid silences and the flow of information sharing drying up.

Reflection helped, and as interviewing skills improved, allowing for increased use of silences helped revealing of the stories and thus a better fluency was noted in later interviews. The clean language approach (Tosey *et al.*, 2014) enhances the fidelity of the participant's inner and outer worldview, avoiding the researcher's metaphors to threaten the authenticity of the findings. In the clean language approach, it is believed that 'these specific questions help us systematically eliminate our own assumptions so that they do not influence us when conducting an interview' (Nehyba and Svojanovský, 2017 p.131). What is particularly refreshing about this style is using the words of the participants to draw deeper into their world, rather than using the researcher's interpretation of their words. Although the interviews did not use a clean language approach, drawing on this new knowledge and implementing the tools allowed the interviewing style to flourish in the right direction. An additional limitation is the possibility of misinterpretation of the qualitative data, along with unintended mistakes.

Interpretation of a qualitative data set cannot be perfect because of contextuality and researcher analysis (Heinrich and Klein, 2021), despite independent transcription and coding assessment. Therefore, this research is mindful of the need for transparency. Challenges for optimum member checking included failed email and telephone communications with participants, and time delays. The time delay was influenced by the clinical role of the researcher and thus lost the opportunity to maximise validity and reflection. Given the research's iterative and pragmatic journey, its external validity is challenged. The findings cannot be extrapolated to a larger population. However, transparency of the work will assist and inform future research.

#### **9.9.7 Interpretation of results**

Another significant limitation was the small data in Phase 1 and thus the interpretation of results. The data was self-reported and independent verification is naturally tricky and potential limitations include reliance on participants memory accuracy or selective memory, under or overstating when recalling their experience. Furthermore, the opportunity for additional analysis was not possible, for example, a test of association to indicate if BMI is correlated with the effectiveness of the device. The sample was not large enough to ensure that outcomes in each category had a realistic chance of being seen. Thus, limiting the exposure of a larger effect size. Additionally, in any future investigation, the length of intervention needs to be considered, along with the sample size.

#### **9.9.8 Loss of contact with PPI group**

Despite efforts, the PPI group was not reconvened due to loss of contact with many of the participants. Embedding PPI activity from beginning to end of this research was a missed opportunity. Even so, the contribution of the PPI that did

occur was invaluable for helping shape the design and increase the confidence associated with the worthiness of continuing the research. Recommendations exist for the rigour of incorporating PPI into research (Price *et al.*, 2018), and so any future research needs to note the steps required to improve rigour.

## **9.10 Summary**

In this chapter, the threads of the findings from the exploratory phase, Phase 1 and Phase 2, have been pulled together. Supporting feasibility for studying this field further and highlights the methodological limitations. The preliminary conceptual framework, and its second and third iteration have demonstrated a close fit to the real-world evidence that has emerged. The next and final chapter focuses on the research implications, lessons learned along the way, and recommendations for further research.

## Chapter 10 – Conclusions

*'No more straining. What an amazing gadget this is, wish I had found it sooner, easy to use, and does what it says on the box' (Amazon, 2021)*

### 10.1 Introduction

In this final chapter, conclusions from the research questions, lessons learned along the way, contribution to practice and knowledge, and implementation of evidence will be presented, followed by recommendations for practice and future research. The work reported in this thesis has explained the scope of the clinical problem and offers suggestions for improving care for women who have rectal emptying difficulties based on pragmatic research. Rectal emptying that is comfortable and complete is an essential aspect of bowel function. Although it is sometimes overlooked, role modelling for toileting training in childhood, an individual's belief system in self-care, and how they react in stressful situations all play a role in reaching bowel health mastery. As a result, the intricacy of bowel function can be explained against the backdrop of what appears to be a simple aspect of human life. Rectal emptying problem and its implications are not mentioned in any of the anticipated new and future technologies for bladder and bowel incontinence. As a result, this study focused on an unproven, patient-centred device designed to help women with obstructed defaecation, secondary to rectocele, manage their rectal emptying issues more successfully and satisfactorily. Overall, improving women's bowel health has been the focus of this work. It has revealed the clinical problem of rectal emptying difficulty in women and contributed to the improvement of care. The contribution to knowledge and clinical practice has been achieved, yet the gaps that remain will continue to drive further investigation. Reflecting on the beginning of this work and its iterative

journey reveals determination and tenacity in a subject that prefers to be left untouched. Only as the weaver steps away from the tapestry, can they truly see the beauty, its flaws, and what could be done differently next time, perhaps a change of thread, a different colour, or size.

## **10.2 Overview**

Drivers for the study were the theoretical positioning of bowel mastery, the scoping review, and the experiential learning and knowledge of the researcher. From here, an exploratory phase was conducted to inform and help shape the design. The study approach was mixed-method using an explanatory sequential design, which examined the use of the patient-centred device employing before and after questionnaires (Phase 1); and inviting the participants for a semi-structured interview (Phase 2). Thirty-six women from a rural county with one secondary care hospital were recruited. From the same sample, 26 women who live with the experience of rectal emptying difficulty were invited to interview.

## **10.3 Summary of the key findings**

Arising from Phase 1, the data suggest that the invention and innovation of the patient-centred device have, so far, provided confidence that for some women with rectal emptying difficulty they will achieve benefit from its use. Use of the device is most likely best positioned before surgical intervention. As Participant 26 summarised:

*I feel this is more of a last resort device after physio, diet and exercise have been tried or if a person is particularly put off by using their fingers (Table 7.12)*

Patients may not report bowel symptoms, and healthcare providers do not necessarily inquire about them. As a result, suddenly introducing questioning about bowel issues and how they deal with them could expose anxiety. Therefore, sensitivity and good consultation skills are necessary to take constructive steps towards effective intervention. Conservative interventions should be provided and tried in primary care until referring onwards to a specialist service, with individual preferences considered. The patient-centred device offers an additional option for the toolkit of conservative interventions. Furthermore, it contributes to providing cost-effective yet high-quality healthcare by reducing unnecessary secondary care referrals, a pillar of the current NHS strategy.

Exposing the lived experience of the participants using interviews in Phase 2 revealed their suffering. Until then, their stories were largely unspoken and unheard. This research gave them a voice. Given the theoretical underpinnings of bowel mastery, driven by social learning theory, self-efficacy, and coping, the complexity of this interplay is unlikely to shift human behaviour easily. Therefore, health care professionals must be adequately prepared to embed sympathetically posed bowel-related questions within their clinical inquiry. Notably, this needs to include questions such as 'do you experience any difficulty with emptying your rectum'. The participants' stories identify the problematic nature of disclosing this intimate detail. Women will continue to suffer in silence without addressing better clinical inquiry.



## **10.4 Lessons learned along the way**

### **10.4.1 Invention and innovation**

The extent of the clinical problem and the urgent need to find solutions for women with rectal emptying difficulty guided the pragmatic investigation in this thesis.

Whilst iterative in nature, the funding opportunity was complicated and partly led to adopting a back-to-front approach to medical device development. However, it is unlikely that a front-to-back approach would have happened since the women's voices were silent, and their needs remained unrecognised. The desire to do the right thing for the patient underpinned this problem-solving, pragmatic style.

Finding solutions to problems at the front line of care warrants a fresh approach.

The need for a deeper understanding of the nature of innovation is vital to capture the creativity and uniqueness of nursing. While nursing is currently experiencing turbulence in workload pressures, safe staffing, and emotional toil, its future will be impacted by its ability to develop and adapt within an increasingly dynamic environment. However, nursing is rich with opportunity. Nonetheless, the process from idea inception to product creation and commercialisation needs to be better understood within the nursing profession and healthcare generally.

Furthermore, their contribution should be encouraged and exploited at each development phase to improve healthcare delivery.

### **10.4.2 Methodological lessons**

Researcher bias and conflict of interest were constant tensions because the researcher was also the inventor and clinician. In other words, identity was integrated and thus open to the risk of confusion. Confusion for the researcher, as in 'which part am I playing now' and possibly similar for others externally.

Therefore, an explanation of researcher identity was a necessity. Despite reflexive attention and candour, these conflicts were not easily resolved. However, full disclosure is featured at every stage including ethics approval, interviewing, and PPI group. Future investigations will require separation of these roles, supported by a research team with an opportunity for critical appraisal. Separation can facilitate direct research contact, increasing integrity and reducing ethical issues. However, the double-agent nature of the researcher and clinician can help bridge the worlds of research and clinical practice, as demonstrated by this thesis. Even so, the triple-agent approach is scant within the literature. As a result, caution must be exercised while deciding on the best research designs for clinicians who play several roles.

Misinterpretation of the data is one of the problems that needs acknowledgment. For instance, being too close to the data because of the triple-agent approach risks critical appraisal. Yet, getting close to the women in this research was vital to allow their voices to be heard, unveil their suffering, and permit their stories to be harnessed. As a result of the difficulty in suspending or withholding researcher closeness, bracketing was not adopted. Although, independent scrutiny facilitated detaching oneself from the intimacy of the stories to allow critical appraisal of the data. An independent assessor reviewed a selection of transcribed interviews and their coding. Verification was achieved through discussion, taking a break, and reintegrating with the data. Additionally, clinical supervision provided welcome sessions to reflect and critique processes. Acknowledging the limitation of data misinterpretation is essential for future research. Yet, this story could not be told without closeness to the women and the data.

The primary stakeholder were the women who uniquely told their story. Only they can express what it is like to experience rectal emptying difficulty. However, a missed opportunity was not including other stakeholders, such as the healthcare professional. The study would have benefited from including their viewpoint through semi-structured interviews and/or focus group (Shah *et al.*, 2009). Notably to help convey experiences, barriers, and attitudes towards helping women with rectal emptying difficulty.

## **10.5 Contribution to Clinical Practice**

This research posed the question ‘does the patient-centred device help women who have rectocele manage obstructive defaecation more effectively and satisfactorily than their usual methods?’. As a result of this research, there is now evidence, albeit still limited, that the sense of incomplete emptying and feeling blocked improved with the use of the patient-centred device. Furthermore, most women reported that the device was better than not using it, with participants reporting positively on preference, self-reported effectiveness, ease of use, and convenience. Consequently, the invention of the patient-centred device has provided a viable alternative option to digitation and presents a pioneering contribution for women with rectal emptying difficulty. The device is commercially available and within the NHS Supplies catalogue and has extended its reach beyond the UK. As previously discussed, the NHS has several offerings to support innovation, yet the device made its way into clinical practice independently against the odds. The innovation journey for the device was not subject to a formal innovation or funding pathway. That notwithstanding, it must be emphasised that NHS Innovations (when in existence) supported the invention

and subsequent innovation, albeit only at an early stage. There was minimal support available for scaling up the roll-out of this device, and this needs to be addressed in the quest for increasing innovation.

## **10.6 Contribution to Knowledge**

The second research question asked served to elicit what the lived experience is like for women who experience difficulty emptying their rectum because of obstructive defaecation due to rectocele. The themes that arose from Phase 2 of the mixed methods approach and the associated quotations uncover the secret world of how women handle and cope with rectal emptying problems. Women were given a voice and the opportunity to reveal, through interviews, their lived experience, which is new and makes a significant contribution to the existing knowledge base. This rich and yet harrowing insight has, until now, been sadly lacking. Without the invention of the patient-centred device, the lid may not have been lifted. How this informs healthcare is a vital matter. Steps must be taken to encourage health professionals to use this new evidence and translate it into their practice, truly adopting an evidence-based practice approach. Thus, healthcare must clinically enquire, by asking their female patients who present with a bladder or bowel dysfunction if there is difficulty with rectal emptying being experienced.

## **10.7 Implementation of evidence**

As previously highlighted, implementation science is essential to improve access to and treatment of rectal emptying difficulty in women. To that end, the successful implementation of the patient-centred device into the therapeutic setting is an important outcome of this thesis. Women can have an alternative option to digitation. The development of an implementation framework aims to

transform practice and enrich healthcare (Figure 9.3). The framework builds on the MRC guidance, development, feasibility/piloting, evaluation, and implementation. A natural progression of this research includes firstly, drawing upon the evidence from this research, the encouraging usability of the patient-centred device combined with improved understanding of the user experience. Secondly to drive scaling up by strengthening PPI, clinical pathway development, review of the device design, a multi-site RCT and spreading innovation nationally and internationally. Thirdly and finally, sustainability by effective leadership, drug tariff submission, information technology (for example smartphone application), social media and shifting organisational culture through HCP engagement.

## **10.8 Recommendations for practice and future research**

In addition to the contributions to practice and knowledge, and evidence implementation, the following recommendations add further comment for practice and future research. With specific focus on clinical practice, research, product design, and availability.

### **10.8.1 Clinical practice**

The research journey initially started in clinical practice, where women who intuitively approached rectal emptying difficulty using digitation (their fingers to empty the rectum) were identified. Travelling this journey recognised the necessity to integrate clinical inquiry about rectal emptying difficulty with women who need to access healthcare. Routinely asking, in a sensitive manner, each woman, if they experience difficulty with rectal emptying, may provide an opportunity for disclosure and avoid unnecessary suffering. Depending on the consultation outcome, some women can be signposted to the patient-centred device option.

Embedding clinical inquiry and self-management intervention options into clinical practice should take advantage of the NICE Clinical Knowledge Summaries on Constipation, which will require updating considering these research findings.

### **10.8.2 Research**

The mixed-method study that has been reported in this thesis has identified that it is feasible to investigate the uptake and use of the patient-centred device for women with rectal emptying difficulty. It is recommended that a multi-site randomised clinical trial be considered, fully funded, and supported by a clinical research network. Inclusion of stakeholders, such as healthcare professionals, and defining areas of focus, for example, comparison with other interventions and cost effectiveness should be considered. Furthermore, the potential of social media is a worthy tool within the methodological design.

### **10.8.3 Product design and availability**

The women who took part in this research provided valuable feedback on the current design of the patient-centred device. This included suggestions to modify the handle length, paddle size, material flexibility, and a preference for different colours. Therefore, the untapped resource of online customer feedback from women who self-purchase the device can and should be used to inform human-centred design. Additionally, Drug Tariff availability of the patient-centred device for women within primary care should be progressed. A formal application to the Drug Tariff is required, and the patient-centred device to be available for usage through the DT1 Form Part B. (CE Marked Class I Non-Sterile Medical Devices).

## 10.9 Summary

The journey captured in this thesis has navigated role modelling for toileting training in childhood, an individual's belief system in looking after themselves, and how they cope in adverse situations helps to elaborate the complexity of bowel function against a backdrop of what can seem to be a simple fact of human life. Seizing a clinical problem in bowel dysfunction highlighted the interconnectedness of invention and innovation and that developing an invention is not sufficient to guarantee effective implementation into healthcare practice. Determining the range of available interventions, the scoping review identified two interventions, which were all healthcare initiated. No self-initiated interventions were identified, thereby highlighting a significant gap in the evidence base. The findings and recommendations arising from this thesis helped address this gap in the evidence base, by identifying those women who can benefit from a patient-centred device that offers a self-initiated alternative to digitation for dealing with rectal emptying difficulty. The use of a metaphor throughout the thesis has facilitated scrutiny, reflection and offered an identity for the research. The women have been given a voice and revealed their weft of lived experience, and their suffering, which is hoped will help to inform clinical practice leading to better care being offered, improved quality of life for women, and further research. This pioneering work has started to break ground on an unspoken subject.

## Bibliography

- ABRAMS, P., CARDOZO, L, WAGG, A, WEIN, A. (EDS) 2017. *Incontinence 6th Edition ICI-ICS*. International Continence Society, Bristol UK, ICI-ICS. International Continence Society.
- ADLER, P. A. & ADLER, P. 2003. The Reluctant Respondent. In: HOLSTEIN, J. A. & GUBRIUM, J. F. (eds.) *Inside Interviewing: New Lenses, New Concerns*. Sage Publications, Inc.
- ADOM, D., HUSSEIN, E. K. & AGYEM, J. A. 2018. Theoretical and conceptual framework: Mandatory ingredients of a quality research. *International journal of scientific research*, 7, 438-441.
- AHSN. 2019. *Academic Health Science Networks* [Online]. Available: <https://www.ahsnnetwork.com/> [Accessed 28 June 2021].
- AIGNER, F., MAIR, D., MASCHER, A., MAIER, H., ZWECKBERGER, A. & MADERSBACHER, H. 2011. Transanal irrigation - A promising strategy of conservative treatment for defaecation disorders; short and medium term results. *International Urogynecology Journal and Pelvic Floor Dysfunction*, 22.
- AJZEN, I. 2002. Perceived Behavioral Control, Self-Efficacy, Locus of Control, and the Theory of Planned Behavior<sup>1</sup>. *Journal of Applied Social Psychology*, 32, 665-683.
- AKERS, R. L. 2013. *Criminological theories: Introduction and evaluation*, Routledge.
- ALAM, P., ROJAS, R. G., ATAN, I. K., MANN, K. & DIETZ, H. P. 2017. The 'bother' of obstructed defecation. *Ultrasound in Obstetrics & Gynecology*, 49, 394-397.
- ALEXANDER, L. L., LAROSA, J. H., BADER, H. & GARFIELD, S. 2020. *New dimensions in women's health*, Jones & Bartlett Learning.
- AMAZON. 2017. *Customer review* [Online]. Available: [https://www.amazon.co.uk/MYAID-Femmeze-Rectocele-Alternative-Realigning/product-reviews/B00EV025P8/ref=cm\\_cr\\_getr\\_d\\_paging\\_btm\\_next\\_4?ie=UTF8&reviewerType=all\\_reviews&pageNumber=4](https://www.amazon.co.uk/MYAID-Femmeze-Rectocele-Alternative-Realigning/product-reviews/B00EV025P8/ref=cm_cr_getr_d_paging_btm_next_4?ie=UTF8&reviewerType=all_reviews&pageNumber=4) [Accessed 14 January 2022].
- AMAZON. 2018. *Customer review* [Online]. Available: [https://www.amazon.co.uk/MYAID-Femmeze-Rectocele-Alternative-Realigning/product-reviews/B00EV025P8/ref=cm\\_cr\\_getr\\_d\\_paging\\_btm\\_prev\\_1?ie=UTF8&reviewerType=all\\_reviews&pageNumber=1](https://www.amazon.co.uk/MYAID-Femmeze-Rectocele-Alternative-Realigning/product-reviews/B00EV025P8/ref=cm_cr_getr_d_paging_btm_prev_1?ie=UTF8&reviewerType=all_reviews&pageNumber=1) [Accessed 14 January 2022].
- AMAZON. 2021. *Customer Review* [Online]. Available: [https://www.amazon.co.uk/product-reviews/B00EV025P8/ref=cm\\_cr\\_arp\\_d\\_paging\\_btm\\_next\\_2?ie=UTF8&reviewerType=all\\_reviews&pageNumber=2](https://www.amazon.co.uk/product-reviews/B00EV025P8/ref=cm_cr_arp_d_paging_btm_next_2?ie=UTF8&reviewerType=all_reviews&pageNumber=2) [Accessed 21 January 2022].
- AMAZON. 2022. *Amazon* [Online]. Available: <https://www.amazon.com/> [Accessed 19 January 2022].
- ARAIN, M., CAMPBELL, M. J., COOPER, C. L. & LANCASTER, G. A. 2010. What is a pilot or feasibility study? A review of current practice and editorial policy. *BMC Medical Research Methodology*, 10, 67.
- AUBERT, M., MEGE, D., LE HUU NHO, R., MEURETTE, G. & SIELEZNEFF, I. 2021. Surgical management of the rectocele – An update. *Journal of Visceral Surgery*, 158, 145-157.
- AUJOULAT, I., MARCOLONGO, R., BONADIMAN, L. & DECCACHE, A. 2008. Reconsidering patient empowerment in chronic illness: a critique of models of self-efficacy and bodily control. *Soc Sci Med*, 66, 1228-39.
- AVORN, J. & FISCHER, M. 2010. 'Bench to behavior': translating comparative effectiveness research into improved clinical practice. *Health Affairs*, 29, 1891-1900.
- AYERS, S. & KRONENFELD, J. J. 2007. Chronic illness and health-seeking information on the Internet. *Health (London)*, 11, 327-347.
- AZRIN, N. & FOXX, R. 1974. Toilet training in less than a day. Champaign. *Illinois: Research Press*.
- AZZOUZ, L. L. & SHARMA, S. 2018. *Physiology, large intestine* [Online]. Available: <https://www.ncbi.nlm.nih.gov/books/NBK507857/> [Accessed 28 April 2021].



- BAGHERI, A. & AKBARI, M. 2018. The Impact of Entrepreneurial Leadership on Nurses' Innovation Behavior. *J Nurs Scholarsh*, 50, 28-35.
- BALLOU, S. & KEEFER, L. 2017. Psychological Interventions for Irritable Bowel Syndrome and Inflammatory Bowel Diseases. *Clin Transl Gastroenterol*, 8, e214-e214.
- BALTZLY, D. 2018. *Stoicism* [Online]. Available: <https://plato.stanford.edu/archives/sum2018/entries/stoicism/> [Accessed 21 January 2022].
- BANDURA, A. 1977a. Self-efficacy: Toward a unifying theory of behavioral change. *Psychological Review*, 84, 191-215.
- BANDURA, A. 1977b. Social learning theory Englewood Cliffs. NJ: Prentice-Hall.
- BANDURA, A. 1991. Social cognitive theory of self-regulation. *Organizational behavior and human decision processes*, 50, 248-287.
- BARFIELD, W. 2019. The process of evolution, human enhancement technology, and cyborgs. *Philosophies*, 4, 10.
- BASHIR, A. & SIZAR, O. 2019. Laxatives. *StatPearls [Internet]*. StatPearls Publishing.
- BAŠKARADA, S. & KORONIOS, A. 2018. A philosophical discussion of qualitative, quantitative, and mixed methods research in social science. *Qualitative Research Journal*.
- BAUER, M. R., HARRIS, L. N., WILEY, J. F., CRESPI, C. M., KRULL, J. L., WEIHS, K. L. & STANTON, A. L. 2016. Dispositional and Situational Avoidance and Approach as Predictors of Physical Symptom Bother Following Breast Cancer Diagnosis. *Annals of Behavioral Medicine*, 50, 370-384.
- BEAUCHAMP, T. L. & CHILDRESS, J. F. 2001. *Principles of biomedical ethics*, Oxford University Press, USA.
- BEKHUIS, E., GOL, J., BURTON, C. & ROSMALEN, J. 2020. Patients' descriptions of the relation between physical symptoms and negative emotions: a qualitative analysis of primary care consultations. *British Journal of General Practice*, 70, e78.
- BELL, B. 2021. Towards abandoning the master's tools: The politics of a universal nursing identity. *Nurs Inq*, 28, e12395-n/a.
- BENNETT, J. W. & CHUNG, K.-T. 2001. Alexander Fleming and the discovery of penicillin. *Advances in Applied Microbiology*. Academic Press.
- BEZERRA, L. R., VASCONCELOS NETO, J. A., VASCONCELOS, C. T., KARBAGE, S. A., LIMA, A. C., FROTA, I. P., ROCHA, A. B., MACEDO, S. R., COELHO, C. F., COSTA, M. K., SOUZA, G. C., REGADAS, S. M. & AUGUSTO, K. L. 2014. Prevalence of unreported bowel symptoms in women with pelvic floor dysfunction and the impact on their quality of life. *Int Urogynecol J*, 25, 927-33.
- BHARUCHA, A. E., ANDERSON, B. & BOUCHOUCHA, M. 2019. More movement with evaluating colonic transit in humans. *Neurogastroenterol Motil*, 31, e13541-n/a.
- BHAT, A. 2020. *Exploratory research: definition, methods, types and examples* [Online]. <https://www.questionpro.com/>. [Accessed 17 July 2020].
- BIBLE GATEWAY. 2022. *Deuteronomy 23:11-13* [Online]. Bible Gateway. Available: <https://www.biblegateway.com/passage/?search=Deuteronomy+23%3A11-13&version=NIV> [Accessed 21 January 2022].
- BIOQUE, M., GONZALEZ-RODRIGUEZ, A., GARCIA-RIZO, C., COBO, J., MONREAL, J. A., USALL, J., SORIA, V., LABAD, J. & GROUP, P. 2020. Targeting the microbiome-gut-brain axis for improving cognition in schizophrenia and major mood disorders: A narrative review. *Progress in Neuro-Psychopharmacology and Biological Psychiatry*, 110130.
- BIRT, L., SCOTT, S., CAVERS, D., CAMPBELL, C. & WALTER, F. 2016. Member Checking: A Tool to Enhance Trustworthiness or Merely a Nod to Validation? *Qual Health Res*, 26, 1802-1811.
- BITKINA, O. V., KIM, H. K. & PARK, J. 2020. Usability and user experience of medical devices: An overview of the current state, analysis methodologies, and future challenges. *International Journal of Industrial Ergonomics*, 76, 102932.

- BLACKWELL, J., SAXENA, S., JAYASOORIYA, N., BOTTLE, A., PETERSEN, I., HOTOPIF, M., ALEXAKIS, C. & POLLOK, R. C. 2020. Prevalence and Duration of Gastrointestinal Symptoms Before Diagnosis of Inflammatory Bowel Disease and Predictors of Timely Specialist Review: A Population-Based Study. *Journal of Crohn's and colitis*.
- BLEAKLEY, A. 2017. *Thinking with Metaphors in Medicine: The State of the Art*, London, London: Routledge.
- BLIND, K., POHLISCH, J. & ZI, A. 2018. Publishing, patenting, and standardization: Motives and barriers of scientists. *Research Policy*, 47, 1185-1197.
- BNF. 2022. *Constipation* [Online]. Available: <https://bnf.nice.org.uk/treatment-summary/constipation.html> [Accessed 14 January 2022].
- BO, K., FRAWLEY, H. C., HAYLEN, B. T., ABRAMOV, Y., ALMEIDA, F. G., BERGHMANS, B., BORTOLINI, M., DUMOULIN, C., GOMES, M. & MCCLURG, D. 2017a. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. *International urogynecology journal*, 28, 191-213.
- BO, K., FRAWLEY, H. C., HAYLEN, B. T., ABRAMOV, Y., ALMEIDA, F. G., BERGHMANS, B., BORTOLINI, M., DUMOULIN, C., GOMES, M., MCCLURG, D., MEIJLINK, J., SHELLY, E., TRABUCO, E., WALKER, C. & WELLS, A. 2017b. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. *NeuroUrol Urodyn*, 36, 221-244.
- BOBZIEN, S. 1997. STOIC CONCEPTIONS OF FREEDOM AND THEIR RELATION TO ETHICS \*. *Bulletin of the Institute of Classical Studies*, 41, 71-89.
- BODENHEIMER, T., LORIG, K., HOLMAN, H. & GRUMBACH, K. 2002. Patient self-management of chronic disease in primary care. *Jama*, 288, 2469-2475.
- BOEHMER, K. R., ABU DABRH, A. M., GIONFRIDDO, M. R., ERWIN, P. & MONTORI, V. M. 2018. Does the chronic care model meet the emerging needs of people living with multimorbidity? A systematic review and thematic synthesis. *PLoS One*, 13, e0190852-e0190852.
- BOLTON, G. 2010. *Reflective Practice: Writing and Professional Development*, Sage Publications Inc.
- BORDAGE, G. 2009. Conceptual frameworks to illuminate and magnify. *Medical education*, 43, 312-319.
- BOYDSTON, J. A. 1969. *The Collected Works of John Dewey, 1882-1953 (37 Volumes)*, Southern Illinois Up.
- BOYLAN, A.-M., LOCOCK, L., THOMSON, R. & STANISZEWSKA, S. 2019. "About sixty per cent I want to do it": Health researchers' attitudes to, and experiences of, patient and public involvement (PPI)—A qualitative interview study. *Health Expectations*, 22, 721-730.
- BRAUN, V. & CLARKE, V. 2006. Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3, 77-101.
- BRAZELTON, T. B. 1962. A child-oriented approach to toilet training. *Pediatrics*, 29, 121-128.
- BRENNAN, D. M. D., WILLIAMS, G. M. D. P. & KRUSKAL, J. M. D. P. 2008. Practical Performance of Defecography for the Evaluation of Constipation and Incontinence. *Semin Ultrasound CT MR*, 29, 420-426.
- BROOKES, S., DINNING, P. & GLADMAN, M. 2009. Neuroanatomy and physiology of colorectal function and defaecation: from basic science to human clinical studies. *Neurogastroenterology & Motility*, 21, 9-19.
- BROWN, H. & GRIMES, C. 2016. Current Trends in Management of Defecatory Dysfunction, Posterior Compartment Prolapse, and Fecal Incontinence. *Curr Obstet Gynecol Rep*, 5, 165-171.

- BROWN, H. W., ROGERS, R. G. & WISE, M. E. 2017. Barriers to seeking care for accidental bowel leakage: a qualitative study. *International Urogynecology Journal*, 28, 543-551.
- BSUG. 2017. *Sacrohysteropexy for Uterine Prolapse (Womb Prolapse)* [Online]. British Society of Urogynaecology. Available: <https://bsug.org.uk/budcms/includes/kcfinder/upload/files/info-leaflets/SHP%20BSUG%20July%202017.pdf> [Accessed 26 January 2022].
- BUGGE, C., ADAMS, E. J., GOPINATH, D. & REID, F. 2013. Pessaries (mechanical devices) for pelvic organ prolapse in women. *Cochrane Database Syst Rev*, CD004010.
- BUNKER, J. P., STANSFELD, S. & POTTER, J. 1996. Freedom, responsibility, and health. *BMJ*, 313, 1582-1584.
- BUSZEWICZ, M., RAIT, G., GRIFFIN, M., NAZARETH, I., PATEL, A., ATKINSON, A., BARLOW, J. & HAINES, A. 2006. Self management of arthritis in primary care: randomised controlled trial. *Bmj*, 333, 879.
- CADEDDU, F., SALIS, F., CIANGOLA, C. I. & MILITO, G. 2015. Biofeedback and electrostimulation: Last chance or first choice for obstructed defecation? *Surgery (United States)*, 157, 405-406.
- CAMBRIDGE UNIVERSITY PRESS. 2021. *Cambridge Dictionary* [Online]. Available: <https://dictionary.cambridge.org/dictionary/english/light-bulb-moment> [Accessed 23 March 2021].
- CAMILLERI, M. 2021. Human Intestinal Barrier: Effects of Stressors, Diet, Prebiotics, and Probiotics. *Clinical and translational gastroenterology*, 12, e00308-e00308.
- CAO, S., GU, M., FENG, M., JIA, Y., ZHAO, Y., CHEN, S., ZHU, L., BO, S. & ZHAO, Q. 2021. Implementation of evidence in preventing medical device-related pressure injury in ICU patients using the i-PARIHS framework. *Journal of Nursing Management*.
- CARLSON, J. A. 2010. Avoiding traps in member checking. *Qualitative Report*, 15, 1102-1113.
- CARPENTER, J. 2008. Metaphors in qualitative research: Shedding light or casting shadows? *Res Nurs Health*, 31, 274-282.
- CARRAGHER, J. & GORMLEY, K. 2017. Leadership and emotional intelligence in nursing and midwifery education and practice: a discussion paper. *J Adv Nurs*, 73, 85-96.
- CARROLL, R. & PRICKETT, S. 2008. *The Bible: Authorized King James Version*, OUP Oxford.
- CAST, A. D. & BURKE, P. J. 2002. A Theory of Self-Esteem. *Social forces*, 80, 1041-1068.
- CASTLE-CLARKE, S., EDWARDS, N. & BUCKINGHAM, H. 2017. Falling short: why the NHS is still struggling to make the most of new innovations. *London: Nuffield Trust*.
- CASTNER, J., SULLIVAN, S. S., TITUS, A. H. & KLINGMAN, K. J. 2016. Strengthening the Role of Nurses in Medical Device Development. *Journal of Professional Nursing*, 32, 300-305.
- CHARMAZ, K. & MCMULLEN, L. M. 2011. *Five ways of doing qualitative analysis: Phenomenological psychology, grounded theory, discourse analysis, narrative research, and intuitive inquiry*, Guilford Press.
- CHATOOR, D. & EMMNAUEL, A. 2009. Constipation and evacuation disorders. *Best Pract Res Clin Gastroenterol*, 23, 517-30.
- CHENG, C., CHAN, A. O. O., HUI, W. M. & LAM, S. K. 2003. Coping strategies, illness perception, anxiety and depression of patients with idiopathic constipation: a population-based study. *Alimentary Pharmacology and Therapeutics*, 18, 319-326.
- CIEZA, A., SABARIEGO, C., BICKENBACH, J. & CHATTERJI, S. 2018. Rethinking disability. *BMC medicine*, 16, 1-5.
- CLARK, M. & BUCHANAN, R. 2020. Weaving Our Strengths. *Textiles and Tapestries*.
- CLARK, N. M., GONG, M. & KACIROTI, N. 2001. A model of self-regulation for control of chronic disease. *Health Education & Behavior*, 28, 769-782.
- COAD, A., NIGHTINGALE, P., STILGOE, J. & VEZZANI, A. 2021. *The dark side of innovation*. Taylor & Francis.

- COHEN, J. 1988. *Statistical Power Analysis for the Behavioral Sciences*. Hillsdale, Erlbaum. Conner, BE (1988). *The Box in the Barn*. Columbus: Highlights for ....
- COLLDÉN, C. & HELLSTRÖM, A. 2018. Value-based healthcare translated: a complementary view of implementation. *BMC Health Services Research*, 18, 681.
- CORBIN, J. M. & STRAUSS, A. 1988. *Unending work and care: Managing chronic illness at home*, Jossey-bass.
- CORNALLY, N. & MCCARTHY, G. 2011. Help-seeking behaviour: A concept analysis. *International Journal of Nursing Practice*, 17, 280-288.
- CQC 2021. *Enabling innovation and adoption in health and social care: Developing a shared view*. Care Quality Commission.
- CRAIG, P., DIEPPE, P., MACINTYRE, S., MICHIE, S., NAZARETH, I. & PETTICREW, M. 2013. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Int J Nurs Stud*, 50, 587-92.
- CRESSWELL, J. W. 2013. *Qualitative Inquiry and Research Design: Choosing Among Five Approaches*, Sage Publications, Inc.
- CRESSWELL, J. W. & PLANO CLARKE, V. L. 2018. *Designing and Conducting Mixed Methods Research*, Sage Publishing.
- CRESSWELL, J. W. & CLARK, V. L. P. 2017. *Designing and conducting mixed methods research*, Sage publications.
- CRYAN, J. F., O'RIORDAN, K. J., COWAN, C. S., SANDHU, K. V., BASTIAANSEN, T. F., BOEHME, M., CODAGNONE, M. G., CUSSOTTO, S., FULLING, C. & GOLUBEVA, A. V. 2019. The microbiota-gut-brain axis. *Physiological reviews*.
- CURTIS, V. & BIRAN, A. 2001. Dirt, Disgust, and Disease: Is Hygiene in Our Genes? *Perspect Biol Med*, 44, 17-31.
- DAHLANDER, L., GANN, D. M. & WALLIN, M. W. 2021. How open is innovation? A retrospective and ideas forward. *Research Policy*, 50, 104218.
- DAMANPOUR, F. & EVAN, W. M. 1984. Organizational innovation and performance: the problem of "organizational lag". *Administrative science quarterly*, 392-409.
- DARWIN, C. 1872. *Disdain, Contempt, Disgust, Pride, etc., Helplessness, Patience, Affirmation and Negation* [Online]. D. Appleton & Company. Available: [https://brocku.ca/MeadProject/Darwin/Darwin\\_1872\\_11.html](https://brocku.ca/MeadProject/Darwin/Darwin_1872_11.html) [Accessed 06.01.2020 2020].
- DAVIS, C. R. & GLASGOW, M. E. S. 2020. An examination of nurse-authored patents: Implications for nursing practice. *Nursing forum (Hillsdale)*, 55, 772-781.
- DE LANDSHEERE, L., MUNAUT, C., NUSGENS, B., MAILLARD, C., RUBOD, C., NISOLLE, M., COSSON, M. & FOIDART, J. M. 2013. Histology of the vaginal wall in women with pelvic organ prolapse: a literature review. *Int Urogynecol J*, 24, 2011-20.
- DE VIGNEMONT, F. 2018. *Bodily Awareness* [Online]. Metaphysics Research Lab, Stanford University. Available: <https://plato.stanford.edu/archives/spr2018/entries/bodily-awareness/> [Accessed 21 January 2022].
- DEMPSEY, L., DOWLING, M., LARKIN, P. & MURPHY, K. 2016. Sensitive Interviewing in Qualitative Research. *Research in Nursing & Health*, 39, 480-490.
- DENZIN, N. K. 2012. Triangulation 2.0. *Journal of mixed methods research*, 6, 80-88.
- DESIGN COUNCIL. 2022. *The seven tenets of human-centred design* [Online]. Available: <https://www.designcouncil.org.uk/news-opinion/seven-tenets-human-centred-design> [Accessed 30 January 2022].
- DI PLINIO, S., PERRUCCI, M. G., ALEMAN, A. & EBISCH, S. J. 2020. I am Me: Brain systems integrate and segregate to establish a multidimensional sense of self. *Neuroimage*, 205, 116284.
- DIETZ, H., BROWN, B., FRIEDMAN, T. & SUBRAMANIAM, N. 2020. Does the presence of a true radiological rectocele increase the likelihood of symptoms of prolapse? *International urogynecology journal*, 1-5.

- DIETZ, H. P., BROWN, B., FRIEDMAN, T. & SUBRAMANIAM, N. 2021. Does the presence of a true radiological rectocele increase the likelihood of symptoms of prolapse? *International Urogynecology Journal*, 32, 2233-2237.
- DIETZ, H. P., CHAVEZ-COLOMA, L., FRIEDMAN, T. & TUREL, F. 2022. Pelvic organ prolapse in nulliparae. *Australian and New Zealand Journal of Obstetrics and Gynaecology*.
- DIETZ, H. P., GÓMEZ, M., ATAN, I. K. & FERREIRA, C. S. W. 2018. Association between vaginal parity and rectocele. *International Urogynecology Journal*.
- DIMITRIOU, N., SHAH, V., STARK, D., MATHEW, R., MILLER, A. S. & YEUNG, J. M. C. 2015. Defecating disorders: A common cause of constipation in women. *Women's Health*, 11, 485-500.
- DIOP, L., GUILLOU, S. & DURAND, H. 2008. Probiotic food supplement reduces stress-induced gastrointestinal symptoms in volunteers: a double-blind, placebo-controlled, randomized trial. *Nutrition research*, 28, 1-5.
- DIPPER, L., MARSHALL, J., BOYLE, M., HERSH, D., BOTTING, N. & CRUICE, M. 2021. Creating a theoretical framework to underpin discourse assessment and intervention in aphasia. *Brain Sciences*, 11, 183.
- DOAEE, M., MORADI-LAKEH, M., NOURMOHAMMADI, A., RAZAVI-RATKI, S. K. & NOJOMI, M. 2014. Management of pelvic organ prolapse and quality of life: a systematic review and meta-analysis. *International Urogynecology Journal*, 25, 153-163.
- DOMECQ, J. P., PRUTSKY, G., ELRAIYAH, T., WANG, Z., NABHAN, M., SHIPPEE, N., BRITO, J. P., BOEHMER, K., HASAN, R. & FIRWANA, B. 2014. Patient engagement in research: a systematic review. *BMC health services research*, 14, 1-9.
- DOMENICHELLO, A. F. & RAMSDEN, C. E. 2019. The silent epidemic of chronic pain in older adults. *Prog Neuropsychopharmacol Biol Psychiatry*, 93, 284-290.
- DOUSKOS, A., PITSOUNI, E., GRIGORIADIS, T. & ATHANASIOU, S. 2017. Surgical management of pelvic organ prolapse: An update. *HJOG*, 16.
- DRAGE, K. J., AGHERA, M., MACKELLAR, P., TWENTYMAN, R., JACQUES, A., CHALMERS, K. J., NEUMANN, P., NURKIC, I. & THOMPSON, J. 2021. The relationship between symptom severity, bother and psychological factors in women with pelvic organ prolapse: A cross-sectional observational study. *Neurourology and Urodynamics*.
- DRUTZ, H. P. & ALARAB, M. 2006. Pelvic organ prolapse: demographics and future growth prospects. *International Urogynecology Journal*, 17, 6-9.
- DUBOIS, J. M. & ANTES, A. L. 2018. Five Dimensions of Research Ethics: A Stakeholder Framework for Creating a Climate of Research Integrity. *Acad Med*, 93, 550-555.
- DUELUND-JAKOBSEN, J., HAAS, S., BUNTZEN, S., LUNDBY, L., BOJE, G. & LAURBERG, S. 2015. Nurse-led clinics can manage faecal incontinence effectively: results from a tertiary referral centre. *Colorectal Dis*, 17, 710-5.
- DUMOULIN, C. 2016. Adult Conservative Management. In: ABRAMS P, CARDOZO L, WAGG A & WEIN A (eds.) *Incontinence*. 6th International Consultation on Incontinence ed.: ICS ICUD.
- DURHAM, W., SYKES, C., PIPER, S. & STOKES, P. 2015. Conceptual frameworks and terminology in doctoral nursing research. *Nurse Res*, 23, 8-12.
- EKINS, S., DIAZ, N., CHUNG, J., MATHEWS, P. & MCMURTRAY, A. 2017. Enabling Anyone to Translate Clinically Relevant Ideas to Therapies. *Pharm Res*, 34, 1-6.
- ELDH, A. C., ALMOST, J., DECORBY-WATSON, K., GIFFORD, W., HARVEY, G., HASSON, H., KENNY, D., MOODIE, S., WALLIN, L. & YOST, J. 2017. Clinical interventions, implementation interventions, and the potential greyness in between - a discussion paper. *BMC Health Serv Res*, 17, 16.
- ELDRIDGE, S. M., CHAN, C. L., CAMPBELL, M. J., BOND, C. M., HOPEWELL, S., THABANE, L. & LANCASTER, G. A. 2016. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *bmj*, 355.

- ENDLER, N. S. 2001. Coronary Heart Disease (CHD), Coping with. In: SMELSER, N. J. & BALTES, P. B. (eds.) *International Encyclopedia of the Social & Behavioral Sciences*. Oxford: Pergamon.
- ERRIDGE, M. 2011. *Talking Shit: getting the message across* [Online]. School of Advanced Study. Available: [https://sas-space.sas.ac.uk/4789/3/0944858\\_FINAL\\_02-09-11.pdf](https://sas-space.sas.ac.uk/4789/3/0944858_FINAL_02-09-11.pdf) [Accessed 24 January 2022].
- ETIKAN, I. 2016. *Comparison of Convenience Sampling and Purposive Sampling*.
- EUROPEAN UNION 1993. COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.
- EUSTICE, S. 2018. *Femmeze : a User's Guide* [Online]. YouTube. Available: [www.youtube.com](http://www.youtube.com) [Accessed 4 September 2018].
- EUSTICE, S., ENDACOTT, R., MORRIS, J., SHANKAR, R. & KENT, B. 2018. Women's experiences of managing digitation: do we ask enough in primary care? *JRSM Open*, 9.
- EUSTICE, S., JAMES, A., ENDACOTT, R. & KENT, B. 2020. Identifying the health care initiated and self-initiated interventions used by women for the management of rectal emptying difficulty secondary to obstructive defecation: a scoping review protocol. *JBI Evidence Synthesis*, Online First.
- FÀBREGUES, S., MOLINA-AZORIN, J. F. & FETTERS, M. D. 2021. Virtual Special Issue on "Quality in Mixed Methods Research". *Journal of Mixed Methods Research*, 15, 146-151.
- FALL, M., ABRAMS, P., GRIFFITHS, D. & VICTOR, A. 2002. The standardisation of terminology of lower urinary tract function: Report from the standardisation sub-committee. *Neurourology and urodynamics*, 21, 167-178.
- FARCHI, T. & SALGE, T.-O. 2017. Shaping innovation in health care: A content analysis of innovation policies in the English NHS, 1948–2015. *Social Science & Medicine*, 192, 143-151.
- FDA. 2022. *Food and Drugs Administration* [Online]. Available: <https://www.fda.gov/> [Accessed 25 January 2022].
- FETTERS, M. D., CURRY, L. A. & CRESWELL, J. W. 2013. Achieving integration in mixed methods designs-principles and practices. *Health Serv Res*, 48, 2134-56.
- FLICK, U. 2017. Mantras and Myths. *Qualitative Inquiry*, 23, 46-57.
- FLOTT, K. M., GRAHAM, C., DARZI, A. & MAYER, E. 2016. Can we use patient-reported feedback to drive change? The challenges of using patient-reported feedback and how they might be addressed. *BMJ Quality & Safety*.
- FORERO, R., NAHIDI, S., DE COSTA, J., MOHSIN, M., FITZGERALD, G., GIBSON, N., MCCARTHY, S. & ABOAGYE-SARFO, P. 2018. Application of four-dimension criteria to assess rigour of qualitative research in emergency medicine. *BMC Health Services Research*, 18, 120.
- FRANKFURT, H. 2018. *Freedom of the Will and the Concept of a Person. Agency And Responsibility*. Routledge.
- FUNNELL, M. M. & ANDERSON, R. M. 2004. Empowerment and self-management of diabetes. *Clinical diabetes*, 22, 123-127.
- GADKE, D. L., KRATOCHWILL, T. R. & GETTINGER, M. 2021. Incorporating feasibility protocols in intervention research. *Journal of School Psychology*, 84, 1-18.
- GALE, N. K., HEATH, G., CAMERON, E., RASHID, S. & REDWOOD, S. 2013. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*, 13, 117.
- GALVIN, B. M., RANDEL, A. E., COLLINS, B. J. & JOHNSON, R. E. 2018. Changing the focus of locus (of control): A targeted review of the locus of control literature and agenda for future research. *Journal of organizational behavior*, 39, 820-833.
- GEARING, R. E. 2004. Bracketing in Research: A Typology. *Qual Health Res*, 14, 1429-1452.
- GENOVESI, C. 2020. Metaphor and what is meant: Metaphorical content, what is said, and contextualism. *Journal of pragmatics*, 157, 17-38.

- GENUS, A. & ISKANDAROVA, M. 2018. Responsible innovation: its institutionalisation and a critique. *Technological Forecasting and Social Change*, 128, 1-9.
- GIANGREGORIO, L. M. & THABANE, L. 2015. Pilot studies and feasibility studies for complex interventions. *Complex Interventions in Health*. London, England: Routledge, 127-135.
- GIANNINI, A., RUSSO, E., CANO, A., CHEDRAUI, P., GOULIS, D. G., LAMBRINOUDAKI, I., LOPES, P., MISHRA, G., MUECK, A., REES, M., SENTURK, L. M., STEVENSON, J. C., STUTE, P., TUOMIKOSKI, P. & SIMONCINI, T. 2018. Current management of pelvic organ prolapse in aging women: EMAS clinical guide. *Maturitas*, 110, 118-123.
- GLASER, B. G. & STRAUSS, A. L. 2017. *Discovery of grounded theory: Strategies for qualitative research*, Routledge.
- GOFFMAN, E. 1963. *Stigma: notes on the management of spoiled identity*, Simom & Schuster Inc.
- GOOGLE. 2022. Google [Online]. Available: <https://www.google.com/> [Accessed 18 January 2022].
- GORMAN, M. E. 1995. Confirmation, disconfirmation, and invention: The case of Alexander Graham Bell and the telephone. *Thinking & Reasoning*, 1, 31-53.
- GREED, C. 2019. Join the queue: Including women's toilet needs in public space. *The Sociological review (Keele)*, 67, 908-926.
- GREEN, H. E. 2014. Use of theoretical and conceptual frameworks in qualitative research. *Nurse researcher*, 21.
- GREENE, J. C. 2006. Toward a methodology of mixed methods social inquiry. *Research in the Schools*, 13, 93-98.
- GREENHALGH 2004. How to Spread Good Ideas. *Report for the National Co-ordinating Centre for NHS Service Delivery and Organisation R & D (NCCSDO)*.
- GREENSPAN, S. I., WIEDER, S. & SIMONS, R. 1998. *The child with special needs: Encouraging intellectual and emotional growth*, Addison-Wesley/Addison Wesley Longman.
- GRIMES, C. L. & LUKACZ, E. S. 2012. Posterior vaginal compartment prolapse and defecatory dysfunction: are they related? *Int Urogynecol J*, 23, 537-51.
- GRIMES, W. R. & STRATTON, M. 2020. Pelvic Floor Dysfunction. *StatPearls [Internet]*.
- GROVE, A., CLARKE, A., CURRIE, G., METCALFE, A., POPE, C. & SEERS, K. 2020. Advancing clinical leadership to improve the implementation of evidence-based practice in surgery: a longitudinal mixed-method study protocol. *Implementation Science*, 15, 104.
- GURLAND, B. H. R. D. P., T. HULL, T. ZUTSHI, M. 2018. High doses of botox to treat levator spasm and obstructed defecation: To repeat or not. *Diseases of the Colon and Rectum*, 61.
- HACKSHAW, A. 2008. Small studies: strengths and limitations. *Eur Respiratory Soc*.
- HAEUSSLER, C. & ASSMUS, A. 2021. Bridging the gap between invention and innovation: Increasing success rates in publicly and industry-funded clinical trials. *Research Policy*, 50, 104155.
- HAGEN, S., STARK, D., GLAZENER, C., DICKSON, S., BARRY, S., ELDERS, A., FRAWLEY, H., GALEA, M. P., LOGAN, J., MCDONALD, A., MCPHERSON, G., MOORE, K. H., NORRIE, J., WALKER, A. & WILSON, D. 2014. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. *Lancet*, 383, 796-806.
- HAIYING, C. D., H. P. KAMISAN ATAN, I. CAUDWELL-HALL, J. GUZMAN ROJAS, R. 2014. Digitation associated with defecation: What does it mean in urogynecological patients? *Neurourology and Urodynamics*, 33, 882-883.
- HAYLEN, B. T., MAHER, C. F., BARBER, M. D., CAMARGO, S., DANDOLU, V., DIGESU, A., GOLDMAN, H. B., HUSER, M., MILANI, A. L., MORAN, P. A., SCHAER, G. N. & WITHAGEN, M. I. J. 2016. An International Urogynecological Association (IUGA) / International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Organ Prolapse (POP). *Neurourology and Urodynamics*, 35, 137-168.

- HEIDELBAUGH, J., MARTINEZ DE ANDINO, N., PINELES, D. & POPPERS, D. M. 2021. Diagnosing Constipation Spectrum Disorders in a Primary Care Setting. *Journal of Clinical Medicine*, 10, 1092.
- HEINRICH, A. & KLEIN, E. 2021. Challenges for the management of qualitative and quantitative data: The example of social policy-related data collections. *Global Social Policy*, 21, 138-143.
- HEWER-RICHARDS, L. & GOODALL, D. 2020. Everybody S\*\*\*s: how defecation stigma reduces care quality in dementia. *Quality in Ageing and Older Adults*.
- HIBBARD, J. & GILBERT, H. 2014. Supporting people to manage their health. *An introduction to patient activation*. London: The King's Fund.
- HICKS, C. W., SAVITT, L., BORDEIANOU, L., WEINSTEIN, M., WAKAMATSU, M. & PULLIAM, S. 2014a. In patients with rectoceles and obstructed defecation syndrome, surgery should be the option of last resort. *Surgery (United States)*, 155, 659-667.
- HICKS, C. W., WEINSTEIN, M., WAKAMATSU, M., SAVITT, L., PULLIAM, S. & BORDEIANOU, L. 2014b. In patients with rectoceles and obstructed defecation syndrome, surgery should be the option of last resort. *Surgery*, 155, 659-67.
- HITE, M. & CURRAN, T. 2020. Biofeedback for Pelvic Floor Disorders. *Clin Colon Rectal Surg*.
- HOFFMANN, T. C., GLASZIOU, P. P., BOUTRON, I., MILNE, R., PERERA, R., MOHER, D., ALTMAN, D. G., BARBOUR, V., MACDONALD, H., JOHNSTON, M., LAMB, S. E., DIXON-WOODS, M., MCCULLOCH, P., WYATT, J. C., CHAN, A.-W. & MICHIE, S. 2014. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ : British Medical Journal*, 348, g1687.
- HOLAHAN, C. J. & MOOS, R. H. 1986. <holahan and moos 1986.pdf>. *Journal of Personality and Social Psychology*, 51, 389-395.
- HOLLOWAY, A. & WATSON, H. E. 2002. Role of self-efficacy and behaviour change. *Int J Nurs Pract*, 8, 106-115.
- HONG, Q. N., PLUYE, P., BUJOLD, M. & WASSEF, M. 2017. Convergent and sequential synthesis designs: implications for conducting and reporting systematic reviews of qualitative and quantitative evidence. *Systematic Reviews*, 6, 61.
- HORNSEY, M. J., BAIN, P. G., HARRIS, E. A., LEBEDEVA, N., KASHIMA, E. S., GUAN, Y., GONZÁLEZ, R., CHEN, S. X. & BLUMEN, S. 2018. How Much Is Enough in a Perfect World? Cultural Variation in Ideal Levels of Happiness, Pleasure, Freedom, Health, Self-Esteem, Longevity, and Intelligence. *Psychological Science*, 0, 0956797618768058.
- HOYT, M. A., AUSTENFELD, J. & STANTON, A. L. 2016. Processing coping methods in expressive essays about stressful experiences: Predictors of health benefit. *Journal of Health Psychology*, 21, 1183-1193.
- HUGHES, K., BELLIS, M. A., HARDCASTLE, K. A., SETHI, D., BUTCHART, A., MIKTON, C., JONES, L. & DUNNE, M. P. 2017. The effect of multiple adverse childhood experiences on health: a systematic review and meta-analysis. *The Lancet Public Health*, 2, e356-e366.
- HYDE, C., DUNN, K. M., HIGGINBOTTOM, A. & CHEW-GRAHAM, C. A. 2016. Process and impact of patient involvement in a systematic review of shared decision making in primary care consultations. *Health Expect*.
- ICD10DATA. 2022. *ICD10Data* [Online]. Available: <https://www.icd10data.com/> [Accessed 14 January 2022].
- IDEO.ORG. 2015. *The field guide to human-centered design* [Online]. Available: [https://d1r3w4d5z5a88i.cloudfront.net/assets/guide/Field%20Guide%20to%20Human-Centered%20Design\\_IDEOorg\\_English-0f60d33bce6b870e7d80f9cc1642c8e7.pdf](https://d1r3w4d5z5a88i.cloudfront.net/assets/guide/Field%20Guide%20to%20Human-Centered%20Design_IDEOorg_English-0f60d33bce6b870e7d80f9cc1642c8e7.pdf) [Accessed 30 January 2022].
- INVOLVE. 2012. Briefing notes for researchers: public involvement in NHS, public health and social care research. In: CENTRE, I. C. (ed.).



- IVERSEN, I. H. 1992. Skinner's early research: From reflexology to operant conditioning. *American Psychologist*, 47, 1318.
- IZETT, M. 2021. *The surgical management of uterine prolapse and the role of mesh*. UCL (University College London).
- JANDA, S. 2006. *Biomechanics of the pelvic floor musculature* [Online]. Available: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1030.6726&rep=rep1&type=pdf> [Accessed 26 January 2022].
- JAO, S.-W. & LEE, W. 2006. *Vaginal insert: US 20060211911 A1* [Online]. Available: <http://www.google.com/patents/US20060211911> [Accessed 9 January 2017].
- JELOVSEK, J. E. & BARBER, M. D. 2006. Women seeking treatment for advanced pelvic organ prolapse have decreased body image and quality of life. *Am J Obstet Gynecol*, 194, 1455-61.
- JELOVSEK, J. E., MAHER, C. & BARBER, M. D. 2007. Pelvic organ prolapse. *The Lancet*, 369, 1027-1038.
- JENKINS, A. L., CRANN, S. E., MONEY, D. M. & O'DOHERTY, K. C. 2018. "Clean and Fresh": Understanding Women's use of Vaginal Hygiene Products. *Sex Roles*, 78, 697-709.
- JOBIN, C., HOOGE, S. & LE MASSON, P. 2019. How proof-of-concept (PoC) can make people be more generative? - Uncovering the Sismo's design of 'generative PoC'.
- JONES, D. 2007. *Moral psychology: The depths of disgust*. Nature Publishing Group.
- JULIOUS, S. A. 2005. Sample size of 12 per group rule of thumb for a pilot study. *Pharmaceutical Statistics*, 4, 287-291.
- KARA, D. 2016. Innovation in nursing practices. *New Trends and Issues Proceedings on Advances in Pure and Applied Sciences*, 170-174.
- KAYA, N., TURAN, N. & AYDIN, G. 2016. Innovation in nursing: A concept analysis. *J Comm Pub Health Nursing*, 2, 2-4.
- KEEFER, L., KIEBLES, J. L. & TAFT, T. H. 2010. The role of self-efficacy in inflammatory bowel disease management: Preliminary validation of a disease-specific measure. *Inflammatory Bowel Diseases*, 17, 614-620.
- KELLY, F. 2011. 'Cooking together disparate things': the role of metaphor in thesis writing. *Innovations in Education and Teaching International*, 48, 429-438.
- KENDIG, C. E. 2016. What is proof of concept research and how does it generate epistemic and ethical categories for future scientific practice? *Science and engineering ethics*, 22, 735-753.
- KIERNAN, M. D. & HILL, M. 2018. Framework analysis: a whole paradigm approach. *Qualitative Research Journal*, 18, 248-261.
- KIM, S., FERNANDEZ, S. & TERRIER, L. 2017. Procrastination, personality traits, and academic performance: When active and passive procrastination tell a different story. *Personality and Individual Differences*, 108, 154-157.
- KIM, Y. S. & KIM, N. 2018. Sex-gender differences in irritable bowel syndrome. *Journal of neurogastroenterology and motility*, 24, 544.
- KINMAN, G., TEOH, K. & HARRISS, A. 2020. The mental health and wellbeing of nurses and midwives in the United Kingdom.
- KITSON, A. L., RYCROFT-MALONE, J., HARVEY, G., MCCORMACK, B., SEERS, K. & TITCHEN, A. 2008. Evaluating the successful implementation of evidence into practice using the PARIHS framework: theoretical and practical challenges. *Implement Sci*, 3, 1.
- KLEIN, S. & COUTURIER, R. 2006. *Eliminator a personal appliance to assist in fecal evacuation for patients with rectal hernia (rectocele): US 20060025782 A1* [Online]. Google. Available: <https://www.google.com/patents/US20060025782> [Accessed 9 January 2017].
- KOECHLIN, H., COAKLEY, R., SCHECHTER, N., WERNER, C. & KOSSOWSKY, J. 2018. The role of emotion regulation in chronic pain: A systematic literature review. *J Psychosom Res*, 107, 38-45.

- KRAEMER DIAZ, A. E., SPEARS JOHNSON, C. R. & ARCURY, T. A. 2013. Variation in the interpretation of scientific integrity in community-based participatory health research. *Social Science & Medicine*, 97, 134-142.
- KRALIK, D., VAN LOON, A. & VISENTIN, K. 2006. Resilience in the chronic illness experience. *Educational action research*, 14, 187-201.
- KRANTZ, H. R. N. B. S. N., STRAIN, B. M. A. C. & TORZEWSKI, J. R. N. M. A. N. M. B. A. C. 2017. Medical device innovation and the value analysis process. *Surgery*, 162, 471-476.
- KRETSER, A., MURPHY, D., BERTUZZI, S., ABRAHAM, T., ALLISON, D. B., BOOR, K. J., DWYER, J., GRANTHAM, A., HARRIS, L. J., HOLLANDER, R., JACOBS-YOUNG, C., ROVITO, S., VAFIADIS, D., WOTEKI, C., WYNDHAM, J. & YADA, R. 2019. Scientific Integrity Principles and Best Practices: Recommendations from a Scientific Integrity Consortium. *Science and Engineering Ethics*, 25, 327-355.
- KROHNE, H. W. 2002. Stress and coping theories. *International Encyclopedia of the Social Behavioral Sciences*, 22, 15163-15170.
- KUHL, J., SANKOWSKI, O. & KRAUSE, D. 2020. Investigation on methods and characteristics in medical device development *Proceedings of the Design Society: DESIGN Conference*, 1, 1969-1978.
- KVALE, S. & BRINKMANN, S. 2009. *Interviews: Learning the Craft of Qualitative Research Interviewing*, Sage Publications, Inc.
- KYRATIS, Y., AHMAD, R. & HOLMES, A. 2012. Technology adoption and implementation in organisations: comparative case studies of 12 English NHS Trusts. *BMJ open*, 2.
- LACY, B. E., MEARIN, F., CHANG, L., CHEY, W. D., LEMBO, A. J., SIMREN, M. & SPILLER, R. 2016. Bowel disorders. *Gastroenterology*, 150, 1393-1407. e5.
- LANCASTER, G. A. & THABANE, L. 2019. Guidelines for reporting non-randomised pilot and feasibility studies. *Pilot and Feasibility Studies*, 5, 114.
- LANE, J. P. & FLAGG, J. L. 2010. Translating three states of knowledge—discovery, invention, and innovation. *Implementation Science*, 5, 9.
- LAWAL, T., MICHAEL, G. & ALIYU, I. 2019. Toilet training and parental help-seeking behavior toward elimination disorders: Our experience in a semi-urban setting. *Medical Journal of Dr. D.Y. Patil Vidyapeeth*, 12, 28-33.
- LAZARUS, R. S. 1993. Coping theory and research: past, present, and future. *Psychosomatic medicine*, 55, 234-247.
- LAZARUS, R. S. & FOLKMAN, S. 1987. Transactional theory and research on emotions and coping. *European Journal of Personality*, 1, 141-169.
- LEE, N. & LINGS, I. 2008. *Doing business research: a guide to theory and practice*, Sage.
- LEEMAN, J., BIRKEN, S. A., POWELL, B. J., ROHWEDER, C. & SHEA, C. M. 2017. Beyond "implementation strategies": classifying the full range of strategies used in implementation science and practice. *Implementation science : IS*, 12, 125-125.
- LEFEVRE, R. & DAVILA, G. W. 2008. Functional disorders: rectocele. *Clinics in colon and rectal surgery*, 21, 129.
- LEHANE, E., LEAHY-WARREN, P., O'RIORDAN, C., SAVAGE, E., DRENNAN, J., O'TUATHAIGH, C., O'CONNOR, M., CORRIGAN, M., BURKE, F., HAYES, M., LYNCH, H., SAHM, L., HEFFERNAN, E., O'KEEFFE, E., BLAKE, C., HORGAN, F. & HEGARTY, J. 2019. Evidence-based practice education for healthcare professions: an expert view. *BMJ Evidence-Based Medicine*, 24, 103-108.
- LEMLEY, M. A. 2011. The Myth of the Sole Inventor. *Michigan Law Review* [Online].
- LEPAGE, E. M., JENSEN, E., PATEL, H. S. & THORNE, N. 2020. S0207The Lack of Adherence to Biofeedback Therapy in Those Diagnosed With Pelvic Floor Dyssynergia. *Official journal of the American College of Gastroenterology | ACG*, 115, S68.
- LESHEM, S. & TRAFFORD, V. 2007. Overlooking the conceptual framework. *Innovations in education and Teaching International*, 44, 93-105.

- LEWIS, S. J. & HEATON, K. W. 1997. Stool form scale as a useful guide to intestinal transit time. *Scand J Gastroenterol*, 32, 920-4.
- LI, X., WEN, J. G., XIE, H., WU, X. D., SHEN, T., YANG, X. Q., WANG, X. Z., CHEN, G. X., YANG, M. F. & DU, Y. K. 2020. Delayed in toilet training association with pediatric lower urinary tract dysfunction: A systematic review and meta-analysis. *J Pediatr Urol*, 16, 352.e1-352.e8.
- LIAMPUTTONG, P. 2013. *Qualitative research methods, 4th edition*, Oxford University Press.
- LIAO, D.-H., ZHAO, J.-B. & GREGERSEN, H. 2009. Gastrointestinal tract modelling in health and disease. *World Journal of Gastroenterology: WJG*, 15, 169.
- LIBERMAN-PINCU, E. & BITAN, Y. 2021. FULE—Functionality, Usability, Look-and-Feel and Evaluation Novel User-Centered Product Design Methodology—Illustrated in the Case of an Autonomous Medical Device. *Applied Sciences*, 11, 985.
- LINCOLN, Y. S. & GUBA, E. G. 1985. *Naturalistic inquiry*, Beverly Hills, Calif., Sage Publications.
- LIU, R. T., WALSH, R. F. & SHEEHAN, A. E. 2019. Prebiotics and probiotics for depression and anxiety: A systematic review and meta-analysis of controlled clinical trials. *Neuroscience & Biobehavioral Reviews*, 102, 13-23.
- LOGROSCINO, G., MARIN, B., PICCININNI, M., ARCUTI, S., CHIÒ, A., HARDIMAN, O., ROONEY, J., ZOCCOLELLA, S., COURATIER, P., PREUX, P.-M. & BEGHI, E. 2018. Referral bias in ALS epidemiological studies. *PLoS One*, 13, e0195821-e0195821.
- LONG, G. & SPALDING, J. L. 1904. *Discourses of Epictetus*, D. Appleton.
- LONGO, A. Obstructed defecation because of rectal pathologies. Novel surgical treatment: stapled transanal rectal resection (STARR). Acts of 14th international colorectal disease symposium. Fort Lauderdale, FL, 2003.
- LORIG, K. R. & HOLMAN, H. R. 2003. Self-management education: history, definition, outcomes, and mechanisms. *Annals of behavioral medicine*, 26, 1-7.
- MAASKAMP, R., MAASKAMP, A. & SALGADO, G. 2014. *Rectocele and cystocele device: WO 2014165195 A1* [Online]. Available: <https://www.google.com/patents/WO2014165195A1> [Accessed 9 January 2017].
- MACHIN, D., CAMPBELL, M. J., TAN, S. B. & TAN, S. H. 2018. *Sample Sizes for Clinical, Laboratory and Epidemiology Studies*, Wiley Online Library.
- MAESTRE, J., EIKEY, E., WARNER, M., YAROSH, S., PATER, J., JACOBS, M., MARCU, G. & SHIH, P. 2018. Conducting Research with Stigmatized Populations: Practices, Challenges, and Lessons Learned. *Computer Supported Cooperative Work*. ACM.
- MAIER, S. L. & MONAHAN, B. A. 2009. How Close Is Too Close? Balancing Closeness And Detachment In Qualitative Research. *Deviant behavior*, 31, 1-32.
- MALLORY S. 2014. *Making a Tapestry—How Did They Do That?* [Online]. Available: <http://www.metmuseum.org/blogs/now-at-the-met/2014/making-a-tapestry> [Accessed 14 January 2022].
- MARJANOVIC, S., ALTENHOFER, M., HOCKING, L., CHATAWAY, J. & LING, T. 2020. Innovating for improved healthcare: Sociotechnical and innovation systems perspectives and lessons from the NHS. *Science and Public Policy*, 47, 283-297.
- MARKHAM, W. A. & AVEYARD, P. 2003. A new theory of health promoting schools based on human functioning, school organisation and pedagogic practice. *Soc Sci Med*, 56, 1209-1220.
- MARSH, D. & FURLONG, P. 2002. A skin not a sweater: Ontology and epistemology in political science. *Theory and methods in political science*, 2, 17-41.
- MARTIN, J. L. & BARNETT, J. 2012. Integrating the results of user research into medical device development: insights from a case study. *BMC Medical Informatics and Decision Making*, 12.
- MARTON, F., CHEUNG, W. M. & CHAN, S. W. Y. 2019. The object of learning in action research and learning study. *Educational Action Research*, 27, 481-495.

- MARTON, G., PIZZOLI, S. F. M., VERGANI, L., MAZZOCCO, K., MONZANI, D., BAILO, L., PANCANI, L. & PRAVETTONI, G. 2021. Patients' health locus of control and preferences about the role that they want to play in the medical decision-making process. *Psychology, health & medicine*, 26, 260-266.
- MATINOLLI, H. M., MIERONKOSKI, R. & SALANTERÄ, S. 2020. Health and medical device development for fundamental care: Scoping review. *Journal of Clinical Nursing*, 29, 1822-1831.
- MAXWELL, J. A. 2013. Conceptual Framework: What Do You Think Is Going On? *Qualitative Research Design: An Interactive Approach*. Third ed.: SAGE Publications, Inc.
- MAXWELL, J. A. 2016. Expanding the history and range of mixed methods research. *Journal of Mixed Methods Research*, 10, 12-27.
- MAY, H. 2021. Socrates: 469 BC–399 BC. *Meet the Philosophers of Ancient Greece*. Routledge.
- MCCLURG, D., BEATTIE, K., LOWE-STRONG, A. & HAGEN, S. 2012. The elephant in the room: the impact of bowel dysfunction on people with multiple sclerosis. *J Assoc of Charter Physiother Women's Health*, Autumn, 13-21.
- MCDONALD, K. M., SUNDARAM, V., BRAVATA, D. M., LEWIS, R., LIN, N., KRAFT, S. A., MCKINNON, M., PAGUNTALAN, H. & OWENS, D. K. 2007. Conceptual frameworks and their application to evaluating care coordination interventions. *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 7: Care Coordination)*. Agency for Healthcare Research and Quality (US).
- MCEWEN, M. & WILLS, E. M. 2017. *Theoretical basis for nursing*, Lippincott Williams & Wilkins.
- MCINTOSH, I. & WRIGHT, S. 2019. Exploring what the notion of 'lived experience' offers for social policy analysis. *Journal of Social Policy*, 48, 449-467.
- MDTI. 2022. *Medical Devices Technology International Ltd (MDTi)* [Online]. Available: <https://www.mdti.co.uk/> [Accessed 19 January 2022].
- MERLEAU-PONTY, M. 1945. *Phenomenology of Perception* (Original *Phénoménologie de la perception*, translated by Donald Landes). Routledge, New York.
- MEYER, I. & RICHTER, H. E. 2015. Impact of fecal incontinence and its treatment on quality of life in women. *Womens Health (Lond)*, 11, 225-238.
- MHRA. 2020. *Medical devices: how to comply with the legal requirements in Great Britain* [Online]. Medicines & Healthcare products Regulatory Agency. Available: <https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements#:~:text=Class%20%20medical%20devices%20do,Britain%20market%20with%20the%20MHRA%20> [Accessed 30 December 2021].
- MHRA. 2022. *Vigilance, safety alerts and guidance: detailed information* [Online]. Available: <https://www.gov.uk/topic/medicines-medical-devices-blood/vigilance-safety-alerts> [Accessed 19 January 2022].
- MICROSOFT. 2022. *Microsoft 365* [Online]. Available: <https://www.microsoft.com/> [Accessed 19 January 2022].
- MILES, M. B. & HUBERMAN, A. M. 1994. *Qualitative data analysis: An expanded sourcebook*, sage.
- MILLEN, N. & WALKER, C. 2001. Overcoming the stigma of chronic illness: strategies for normalisation of a 'spoiled identity'. *Health Sociology Review*, 10, 89-97.
- MILSOM, I. & GYHAGEN, M. 2019. Breaking news in the prediction of pelvic floor disorders. *Best Pract Res Clin Obstet Gynaecol*, 54, 41-48.
- MIMURA, T., ROY, A. J., STORRIE, J. B. & KAMM, M. A. 2000. Treatment of impaired defecation associated with rectocele by behavioral retraining (biofeedback). *Diseases of the colon & rectum*, 43, 1267-1272.
- MIND. 2021. *Celebrity Support* [Online]. Available: <https://www.mind.org.uk/about-us/celebrity-support/> [Accessed 19 March 2021].

- MITSUHASHI, S., BALLOU, S., JIANG, Z. G., HIRSCH, W., NEE, J., ITURRINO, J., CHENG, V. & LEMBO, A. 2018. Characterizing Normal Bowel Frequency and Consistency in a Representative Sample of Adults in the United States (NHANES). *Official journal of the American College of Gastroenterology | ACG*, 113, 115-123.
- MOHAMMADI, D. 2016. Talking faecal transplant. *The Lancet Gastroenterology & Hepatology*, 1, 12.
- MOHER, D., LIBERATI, A., TETZLAFF, J., ALTMAN, D. G. & GROUP, P. 2009. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS med*, 6, e1000097.
- MOORE, G. F., AUDREY, S., BARKER, M., BOND, L., BONELL, C., HARDEMAN, W., MOORE, L., O'CATHAIN, A., TINATI, T. & WIGHT, D. 2015. Process evaluation of complex interventions: Medical Research Council guidance. *bmj*, 350, h1258.
- MORAN-ELLIS, J., ALEXANDER, V. D., CRONIN, A., DICKINSON, M., FIELDING, J., SLENEY, J. & THOMAS, H. 2006. Triangulation and integration: processes, claims and implications. *Qualitative Research*, 6, 45-59.
- MORGAN, D. L. 2014. Pragmatism as a Paradigm for Social Research. *Qualitative Inquiry*, 20, 1045-1053.
- MUKHTAR, K., NAWAZ, H. & ABID, S. 2019. Functional gastrointestinal disorders and gut-brain axis: What does the future hold? *World journal of gastroenterology*, 25, 552.
- MUNN, Z., AROMATARIS, E., TUFANARU, C., STERN, C., PORRITT, K., FARROW, J., LOCKWOOD, C., STEPHENSON, M., MOOLA, S. & LIZARONDO, L. 2019. The development of software to support multiple systematic review types: the Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information (JBI SUMARI). *International journal of evidence-based healthcare*, 17, 36-43.
- MUNN, Z., PETERS, M. D. J., STERN, C., TUFANARU, C., MCARTHUR, A. & AROMATARIS, E. 2018. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Medical Research Methodology*, 18, 143.
- MURAD-REGADAS, S. M., REGADAS, F. S. P., RODRIGUES, L. V., FERNANDES, G. O. D. S., BUCHEN, G. & KENMOTI, V. T. 2012. Management of patients with rectocele, multiple pelvic floor dysfunctions and obstructed defecation syndrome. *Arquivos de gastroenterologia*, 49, 135-142.
- MUSSELL, M., KROENKE, K., SPITZER, R. L., WILLIAMS, J. B. W., HERZOG, W. & LÖWE, B. 2008. Gastrointestinal symptoms in primary care: Prevalence and association with depression and anxiety. *Journal of Psychosomatic Research*, 64, 605-612.
- MUSTAIN, W. C. 2017. Functional Disorders: Rectocele. *Clin Colon Rectal Surg*, 30, 63-75.
- NARASIMHAN, M., ALLOTEY, P. & HARDON, A. 2019. Self care interventions to advance health and wellbeing: a conceptual framework to inform normative guidance. *BMJ*, 365, l688.
- NARAYANAN, S. P. & BHARUCHA, A. E. 2019. A practical guide to biofeedback therapy for pelvic floor disorders. *Current gastroenterology reports*, 21, 1-8.
- NATIONAL ACADEMIES OF SCIENCES, E. & MEDICINE 2016. *Ending discrimination against people with mental and substance use disorders: The evidence for stigma change*, National Academies Press.
- NAYLOR, C., DAS, P., ROSS, S., HONEYMAN, M., THOMPSON, J. & GILBERT, H. 2016. Bringing together physical and mental health. *King's Fund*.
- NEELS, H., TJALMA, W. A., WYNDAELE, J. J., DE WACHTER, S., WYNDAELE, M. & VERMANDEL, A. 2016. Knowledge of the pelvic floor in menopausal women and in peripartum women. *J Phys Ther Sci*, 28, 3020-3029.
- NEHYBA, J. & SVOJANOVSKÝ, P. 2017. Clean Language as a data collection tool. *Becoming a teacher: The dance between tacit and explicit knowledge*, 130-147.

- NETTO, M. B., PAULA, J. C. D., BASTOS, C. R., SOARES, D. G., CASTRO, N. C. T. D., SOUSA, K. K. D. V., CARMO, A. V. D., MIRANDA, R. L. D., MRAD, F. C. D. C. & BESSA JR, J. D. 2021. Personal and familial factors associated with toilet training. *International braz j urol*, 47, 169-177.
- NHS. 2019. *How it's performed -Hysterectomy* [Online]. Available: <https://www.nhs.uk/conditions/hysterectomy/what-happens/> [Accessed 26 January 2022].
- NHS. 2020. *Colostomy* [Online]. Available: <https://www.nhs.uk/conditions/colostomy/> [Accessed 22 January 2022].
- NHS. 2021a. *Accelerated Access Collaborative* [Online]. National Health Service. Available: <https://www.england.nhs.uk/aac/what-we-do/how-can-the-aac-help-me/> [Accessed 28 June 2021].
- NHS. 2021b. *Pelvic organ prolapse* [Online]. Available: <https://www.nhs.uk/conditions/pelvic-organ-prolapse/> [Accessed 14 January 2022].
- NHS BUSINESS SERVICES AUTHORITY. 2022a. *Drug Tariff Part IX information* [Online]. Available: <https://www.nhsbsa.nhs.uk/manufacturers-and-suppliers/drug-tariff-part-ix-information> [Accessed 21 January 2022].
- NHS BUSINESS SERVICES AUTHORITY. 2022b. *NHS Prescription Services* [Online]. Available: <https://www.nhsbsa.nhs.uk/nhs-prescription-services> [Accessed 21 January 2022].
- NHS ENGLAND. 2013. *Sacral Nerve Stimulation for Faecal Incontinence* [Online]. Available: <https://www.england.nhs.uk/wp-content/uploads/2018/07/Sacral-nerve-stimulation-for-faecal-incontinence-Adult.pdf> [Accessed 14 January 2022].
- NHS ENGLAND 2019. The NHS Long Term Plan.
- NICE. 2018. *Peristeen transanal irrigation system for managing bowel dysfunction, Medical technologies guidance [MTG36]* [Online]. Available: <https://www.nice.org.uk/guidance/mtg36> [Accessed 14 January 2022].
- NICE 2019. Urinary incontinence and pelvic organ prolapse in women: management:© NICE (2019) Urinary incontinence and pelvic organ prolapse in women: Management. *BJU Int*, 123, 777-803.
- NICE. 2021. *Constipation* [Online]. National Institute for Health and Care Excellence. Available: <https://cks.nice.org.uk/topics/constipation/> [Accessed 21 January 2022].
- NIHR HORIZON SCANNING CENTRE 2014. New and emerging technologies for urinary and faecal incontinence. University of Birmingham.
- NILSEN, P. 2015. Making sense of implementation theories, models and frameworks. *Implement Sci*, 10, 53.
- NMC 2018. *The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates*, Nursing and Midwifery Council
- NOELTING, J., EATON, J. E., CHOUNG, R. S., ZINSMEISTER, A. R., LOCKE, G. R., 3RD & BHARUCHA, A. E. 2016. The incidence rate and characteristics of clinically diagnosed defecatory disorders in the community. *Neurogastroenterol Motil*, 28, 1690-1697.
- NOYES, J., BOOTH, A., MOORE, G., FLEMMING, K., TUNÇALP, Ö. & SHAKIBAZADEH, E. 2019. Synthesising quantitative and qualitative evidence to inform guidelines on complex interventions: clarifying the purposes, designs and outlining some methods. *BMJ Global Health*, 4, e000893.
- O'CATHAIN, A., MURPHY, E. & NICHOLL, J. 2008. The quality of mixed methods studies in health services research. *Journal of health services research & policy*, 13, 92-98.
- O'CATHAIN, A., MURPHY, E. & NICHOLL, J. 2010. Three techniques for integrating data in mixed methods studies. *BMJ*, 341.
- O'CONNOR, C. & JOFFE, H. 2020. Intercoder Reliability in Qualitative Research: Debates and Practical Guidelines. *International Journal of Qualitative Methods*, 19, 1609406919899220.

- PALLANT, J. 2020. *SPSS survival manual: A step by step guide to data analysis using IBM SPSS*, Routledge.
- PALSSON, O. S., WHITEHEAD, W., TÖRNBLOM, H., SPERBER, A. D. & SIMREN, M. 2020. Prevalence of Rome IV functional bowel disorders among adults in the United States, Canada, and the United Kingdom. *Gastroenterology*, 158, 1262-1273. e3.
- PANNUCCI, C. J. & WILKINS, E. G. 2010. Identifying and Avoiding Bias in Research. *Plastic and reconstructive surgery*, 126, 619-625.
- PARK, C. L., FINKELSTEIN-FOX, L., RUSSELL, B. S., FENDRICH, M., HUTCHISON, M. & BECKER, J. 2021. Americans' distress early in the COVID-19 pandemic: Protective resources and coping strategies. *Psychological Trauma: Theory, Research, Practice, and Policy*, No Pagination Specified-No Pagination Specified.
- PATERSON, B. L., RUSSELL, C. & THORNE, S. 2001. Critical analysis of everyday self-care decision making in chronic illness. *J Adv Nurs*, 35, 335-341.
- PETERS, M., GODFREY, C., MCINERNEY, P., MUNN, Z., TRICCO, A. & KHALIL, H. 2020. Chapter 11: Scoping Reviews (2020 version). *Joanna Briggs Institute Reviewer's Manual, JBI*.
- PETERS, M. D., GODFREY, C. M., KHALIL, H., MCINERNEY, P., PARKER, D. & SOARES, C. B. 2015. Guidance for conducting systematic scoping reviews. *Int J Evid Based Healthc*, 13, 141-6.
- PLUYE, P., GAGNON, M.-P., GRIFFITHS, F. & JOHNSON-LAFLEUR, J. 2009. A scoring system for appraising mixed methods research, and concomitantly appraising qualitative, quantitative and mixed methods primary studies in Mixed Studies Reviews. *Int J Nurs Stud*, 46, 529-546.
- PODZEMNY, V., PESCATORI, L. C. & PESCATORI, M. 2015. Management of obstructed defecation. *World Journal of Gastroenterology*, 21, 1053-1060.
- POLIT, D. & HUNGLER, B. 1994. Essentials of nursing research: Methods, appraisal, asid utilization.
- POPE, C., ZIEBLAND, S. & MAYS, N. 2000. Analysing qualitative data. *Bmj*, 320, 114-116.
- POSTON, G., TAIT, D., O'CONNELL, S., BENNETT, A. & BERENDSE, S. 2011. Diagnosis and management of colorectal cancer: summary of NICE guidance. *Bmj*, 343.
- POVEY, R., CONNER, M., SPARKS, P., JAMES, R. & SHEPHERD, R. 2000. Application of the Theory of Planned Behaviour to two dietary behaviours: Roles of perceived control and self-efficacy. *British Journal of Health Psychology*, 5, 121-139.
- POWNER, L. C. 2014. *Empirical research and writing: A political science student's practical guide*, CQ Press.
- PREYE ROBERT, C. 2020. Understanding the concept of knowledge gap and knowledge expansion: A theoretical perspective. 7, 78-92.
- PRICE, A., SCHROTER, S., SNOW, R., HICKS, M., HARMSTON, R., STANISZEWSKA, S., PARKER, S. & RICHARDS, T. 2018. Frequency of reporting on patient and public involvement (PPI) in research studies published in a general medical journal: a descriptive study. *BMJ Open*, 8, e020452.
- PRICE, N., JACKSON, S. R., AVERY, K., BROOKES, S. T. & ABRAMS, P. 2006. Development and psychometric evaluation of the ICIQ Vaginal Symptoms Questionnaire: the ICIQ-VS. *BJOG*, 113, 700-12.
- PROCTOR, M. J. M., W. COLLIE, M. H. S. 2016. Sacral nerve stimulation to treat failure of defecation and constipation as an alternative to surgical intervention. *Colorectal Disease*, 18, 63.
- PUBLIC HEALTH ENGLAND. 2018. *Introduction to logic models* [Online]. Available: <https://www.gov.uk/government/publications/evaluation-in-health-and-well-being-overview/introduction-to-logic-models> [Accessed 17 June 2021].
- QSR INTERNATIONAL 2016. NVivo qualitative data analysis Software. *In: INTERNATIONAL, Q. (ed.) NVivo qualitative data analysis Software*. NVivo 11 ed.

- QUAGHEBEUR, J., PETROS, P., WYNDAELE, J.-J. & DE WACHTER, S. 2021. Pelvic-floor function, dysfunction, and treatment. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 265, 143-149.
- QUILTER-PINNER, H. & MUIR, R. 2015. *Improved circulation: Unleashing innovation across the NHS*, IPPR.
- RACANIELLO, E., TERZONI, S., ACCARDI, R., RICCI, C., BOCCASANTA, P. & DESTREBECQ, A. 2015. Quality of life of patients undergoing surgery for obstructed defecation syndrome: A before-after study. *International Journal of Surgery*, 21, 18-21.
- RACCHI, M., GOVONI, S., LUCHELLI, A., CAPONE, L. & GIOVAGNONI, E. 2016. Insights into the definition of terms in European medical device regulation. *Expert review of medical devices*, 13, 907-917.
- RAMSTER, G., GREED, C. & BICHARD, J.-A. 2018. How inclusion can exclude: The case of public toilet provision for women. *Built Environment*, 44, 52-76.
- RAO, S. S., BENNINGA, M. A., BHARUCHA, A. E., CHIARIONI, G., DI LORENZO, C. & WHITEHEAD, W. E. 2015. ANMS-ESNM position paper and consensus guidelines on biofeedback therapy for anorectal disorders. *Neurogastroenterology & Motility*, 27, 594-609.
- RAO, S. S. C., SEATON, K., MILLER, M. J., SCHULZE, K., BROWN, C. K., PAULSON, J. & ZIMMERMAN, B. 2007. Psychological profiles and quality of life differ between patients with dyssynergia and those with slow transit constipation. *Journal of Psychosomatic Research*, 63, 441-449.
- RAPPAPORT, J. 1984. Studies in empowerment: Introduction to the issue. *Prevention in human services*, 3, 1-7.
- RASMUSSEN, P., HENDERSON, A., ANDREW, N. & CONROY, T. 2018. Factors influencing registered nurses' perceptions of their professional identity: An integrative literature review. *The Journal of Continuing Education in Nursing*, 49, 225-232.
- RCN 2019. RCN employment survey 2019. Royal College of Nursing.
- REINWALDS, M., BLIXTER, A. & CARLSSON, E. 2018. Living with a resected rectum after rectal cancer surgery—Struggling not to let bowel function control life. *Journal of clinical nursing*, 27, e623-e634.
- RESNIC, F. S. & MATHENY, M. E. 2018. Medical Devices in the Real World. *N Engl J Med*, 378, 595-597.
- REVIEWMETA. 2021. *MYAID Femmeze, a Device for Realigning Rectocele, Assists in Relieving Constipation* [Online]. Available: <https://reviewmeta.com/amazon-uk/B00EV025P8> [Accessed 22 March 2021].
- RICHARDSON, D. & ROGERS, J. 2017. Toilet training for children with additional needs. *Journal of Health Visiting*, 5, 492-494.
- RODGERS, W. M., CONNER, M. & MURRAY, T. C. 2008. Distinguishing among perceived control, perceived difficulty, and self-efficacy as determinants of intentions and behaviours. *Br J Soc Psychol*, 47, 607-630.
- ROMANO, M. 2017. Are similes and metaphors interchangeable?: A case study in opinion discourse. *Review of Cognitive Linguistics. Published under the auspices of the Spanish Cognitive Linguistics Association*, 15, 1-33.
- ROME FOUNDATION. 2016. *Rome IV Diagnostic Criteria* [Online]. Available: <https://theromefoundation.org/about/> [Accessed 14 January 2022].
- ROTH, S. & COHEN, L. J. 1986. Approach, avoidance, and coping with stress. *American Psychologist*, 813-819.
- ROWLEY, J. 2014. Designing and using research questionnaires. *Management Research Review*, 37, 308-330.
- ROZIN, P. & FALLON, A. E. 1987. A perspective on disgust. *Psychological review*, 94, 23.
- RUGG, D. 2010. An introduction to triangulation. *Switzerland: UNAIDS Monitoring and Evaluation Division*.



- RUSSELL, B., BUSWELL, M., NORTON, C., MALONE, J. R., HARARI, D., HARWOOD, R., ROE, B., FADER, M., DRENNAN, V. M., BUNN, F. & GOODMAN, C. 2017. Supporting people living with dementia and faecal incontinence. *Br J Community Nurs*, 22, 110-114.
- SACKETT, D. L. 1997. Evidence-based medicine. *Seminars in Perinatology*, 21, 3-5.
- SARKIES, M., ROBINSON, S., LUDWICK, T., BRAITHWAITE, J., NILSEN, P., AARONS, G., WEINER, B. J. & MOULLIN, J. 2021. Understanding implementation science from the standpoint of health organisation and management: an interdisciplinary exploration of selected theories, models and frameworks. *Journal of Health Organization and Management*.
- SARMA, H., D'ESTE, C., AHMED, T., BOSSERT, T. J. & BANWELL, C. 2021. Developing a conceptual framework for implementation science to evaluate a nutrition intervention scaled-up in a real-world setting. *Public health nutrition*, 24, s7-s22.
- SCHLOEMER, T. & SCHRÖDER-BÄCK, P. 2018. Criteria for evaluating transferability of health interventions: a systematic review and thematic synthesis. *Implementation Science*, 13, 88.
- SCHLOTELBURG, M. 2006. Design protection for technical products. *Journal of intellectual property law & practice*, 1, 675-678.
- SCHRAW, G., WADKINS, T. & OLAFSON, L. 2007. Doing the things we do: A grounded theory of academic procrastination. *Journal of Educational Psychology*, 99, 12-25.
- SCOTT, J. 2017. *Social network analysis*, Sage.
- SEKHON, M., CARTWRIGHT, M. & FRANCIS, J. J. 2017. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Services Research*, 17, 88.
- SHAH, S. G. S., ROBINSON, I. & ALSHAWI, S. 2009. Developing medical device technologies from users' perspectives: a theoretical framework for involving users in the development process. *International journal of technology assessment in health care*, 25, 514-521.
- SHARMA, S. & AGARWAL, B. B. 2012. Scoring systems in evaluation of constipation and obstructed defecation syndrome (ODS). *Journal International Medical Sciences Academy*, 25, 57-59.
- SIM, J. & LEWIS, M. 2012. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol*, 65, 301-8.
- SIMPSON, E. E. A. 2016. Chapter 57 - Stress and Coping in the Menopause. In: FINK, G. (ed.) *Stress: Concepts, Cognition, Emotion, and Behavior*. San Diego: Academic Press.
- SIMREN, M., PALSSON, O. S. & WHITEHEAD, W. E. 2017. Update on Rome IV criteria for colorectal disorders: implications for clinical practice. *Current gastroenterology reports*, 19, 15.
- SINGAL, A. G., HIGGINS, P. D. R. & WALJEE, A. K. 2014. A primer on effectiveness and efficacy trials. *Clinical and translational gastroenterology*, 5, e45-e45.
- SKILTON, E., ASLAM, M., YEUNG, J., GAO, F. & MELODY, T. 2016. Embedding patient and public involvement within research - How to set up a research patient ambassador group within a NHS trust. *Journal of the Intensive Care Society*, 17, 234-237.
- SKINNER, E. A., EDGE, K., ALTMAN, J. & SHERWOOD, H. 2003. Searching for the structure of coping: a review and critique of category systems for classifying ways of coping. *Psychological bulletin*, 129, 216.
- SKIVINGTON, K., MATTHEWS, L., SIMPSON, S. A., CRAIG, P., BAIRD, J., BLAZEY, J., BOYD, K. A., CRAIG, N., FRENCH, D. & MCINTOSH, E. 2021. A new framework for developing and evaluating complex interventions: Update of Medical Research Council guidance.
- SMITH, J. & FIRTH, J. 2011. Qualitative data analysis: the framework approach. *Nurse researcher*, 18, 52-62.
- SOKOL, E. R. 2017. Initial assessment of device mechanism of action and patient acceptance of a novel medical device: feasibility study of vaginal bowel control therapy for the treatment of faecal incontinence. *BMJ Innovations*, 3, 221-226.

- SPERBER, A. D., DUMITRASCU, D., FUKUDO, S., GERSON, C., GHOSHAL, U. C., GWEE, K. A., HUNGIN, A. P. S., KANG, J.-Y., MINHU, C., SCHMULSON, M., BOLOTIN, A., FRIGER, M., FREUD, T. & WHITEHEAD, W. 2017. The global prevalence of IBS in adults remains elusive due to the heterogeneity of studies: a Rome Foundation working team literature review. *Gut*, 66, 1075-1082.
- SRIKRISHNA, S., ROBINSON, D. & CARDOZO, L. 2010. Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. *Int Urogynecol J*, 21, 523-8.
- STALLMAN, H. M. 2020. Health theory of coping. *Australian psychologist*, 55, 295-306.
- STARR, J. A., DROBNIS, E. Z., LENGGER, S., PARROT, J., BARRIER, B. & FOSTER, R. 2013. Outcomes of a comprehensive nonsurgical approach to pelvic floor rehabilitation for urinary symptoms, defecatory dysfunction, and pelvic pain. *Female pelvic medicine & reconstructive surgery*, 19, 260-265.
- STATISTICS, O. F. N. 2016. Population Estimates for UK, England and Wales, Scotland and Northern Ireland mid-2015.
- STEEN, M. 2011. Tensions in human-centred design. *CoDesign*, 7, 45-60.
- STRATFORD, E. & BRADSHAW, M. 2016. Qualitative Research Design and Rigour. In: HAY, I. (ed.) *Qualitative Research Methods in Human Geography*. Fourth ed.: Oxford University Press.
- STRESS NO MORE. 2016. <http://www.stressnomore.co.uk/femmeze-vagina-trainer-91842.html> [Online]. Available: <http://www.stressnomore.co.uk/> [Accessed 15 Dec 2016].
- STRESS NO MORE. 2017. *Customer review* [Online]. Available: <https://www.stressnomore.co.uk/femmeze-vagina-trainer-91842.html> [Accessed 14 January 2022].
- SU, S. 2018. The Danger of Doing Power Calculations Using Only Descriptive Statistics. *Biostatistics and Biometrics Open Access Journal*, 5, 113-114.
- SUGRUE, J. & KOBAK, W. 2016. Management of patients with rectocele. *Seminars in Colon and Rectal Surgery*, 27, 51-58.
- SULTAN, A. H., MONGA, A., LEE, J., EMMANUEL, A., NORTON, C., SANTORO, G., HULL, T., BERGHMANS, B., BRODY, S. & HAYLEN, B. T. 2016. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female anorectal dysfunction. *Neurourol Urodyn*.
- SUNG, V. W., RARDIN, C. R., MYERS, D. L., RAKER, C. A. & LASALA, C. A. 2012. Changes in bowel symptoms 1 year after rectocele repair. *American Journal of Obstetrics and Gynecology*, 207, 423.
- SWEDBERG, R. 2018. On the uses of exploratory research and exploratory. *Producing Knowledge. Forthcoming*.
- SWEDBERG, R. 2020. Exploratory research. *The production of knowledge: Enhancing progress in social science*, 17-41.
- TACK, J., STANGHELLINI, V., MEARIN, F., YIANNAKOU, Y., LAYER, P., COFFIN, B., SIMREN, M., MACKINNON, J., WISEMAN, G. & MARCINIAC, A. 2019. Economic burden of moderate to severe irritable bowel syndrome with constipation in six European countries. *BMC gastroenterology*, 19, 69.
- TAHMASSIAN, K. & MOGHADAM, N. J. 2011. Relationship between self-efficacy and symptoms of anxiety, depression, worry and social avoidance in a normal sample of students. *Iranian journal of psychiatry and behavioral sciences*, 5, 91.
- TAN, C., GENG, J., TANG, J. & YANG, X. 2020. The relationship between obstructed defecation and true rectocele in patients with pelvic organ prolapse. *Scientific reports*, 10, 1-6.
- TARRICONE, R., BOSCOLO, P. R. & ARMENI, P. 2016. What type of clinical evidence is needed to assess medical devices? *European Respiratory Review*, 25, 259.
- TASHAKKORI, A., JOHNSON, R. B. & TEDDLIE, C. 2020. Mixed Methods: The Third Methodological Movement. *Foundations of Mixed Methods Research: Integrating Quantitative and Qualitative Approaches in the Social and Behavioral Sciences*.

- TAUBMAN, B., BLUM, N. J. & NEMETH, N. 2003. Children who hide while defecating before they have completed toilet training: a prospective study. *Archives of pediatrics & adolescent medicine*, 157, 1190-1192.
- TEDDLIE, C. & TASHAKKORI, A. 2003. Major issues and controversies in the use of mixed methods in the social and behavioral sciences. *Handbook of mixed methods in social & behavioral research*, 3-50.
- THOMAS, C., QUILTER-PINNER, H. & VERMA, P. 2020. The Innovation Lottery. Upgrading the spread of innovation in the NHS. *Institute for Public Policy Research*.
- THORPE, G., ARTHUR, A. & MCARTHUR, M. 2016. Adjusting to bodily change following stoma formation: a phenomenological study. *Disability and rehabilitation*, 38, 1791-1802.
- THURSBY, E. & JUGE, N. 2017. Introduction to the human gut microbiota. *Biochemical Journal*, 474, 1823-1836.
- TILLOU, J. & POYLIN, V. 2016. Functional Disorders: Slow-Transit Constipation. *Clinics in Colon and Rectal Surgery*, 30, 076-086.
- TINCELLO, D. G., OWEN, R. K., SLACK, M. C. & ABRAMS, K. R. 2013. Validation of the Patient Global Impression scales for use in detrusor overactivity: secondary analysis of the RELAX study. *BJOG*, 120, 212-216.
- TOBIN, G. A. & BEGLEY, C. M. 2004. Methodological rigour within a qualitative framework. *J Adv Nurs*, 48, 388-396.
- TOSEY, P., LAWLEY, J. & MEESE, R. 2014. Eliciting Metaphor through Clean Language: An Innovation in Qualitative Research. *British Journal of Management*, 25, 629-646.
- TRAFIMOW, D., SHEERAN, P., CONNER, M. & FINLAY, K. A. 2002. Evidence that perceived behavioural control is a multidimensional construct: Perceived control and perceived difficulty. *Br J Soc Psychol*, 41, 101-121.
- TREW, J. L. 2011. Exploring the roles of approach and avoidance in depression: An integrative model. *Clinical Psychology Review*, 31, 1156-1168.
- TRICCO, A. C., LILLIE, E., ZARIN, W., O'BRIEN, K. K., COLQUHOUN, H., LEVAC, D., MOHER, D., PETERS, M. D. J., HORSLEY, T., WEEKS, L., HEMPEL, S., AKL, E. A., CHANG, C., MCGOWAN, J., STEWART, L., HARTLING, L., ALDCROFT, A., WILSON, M. G., GARRITTY, C., LEWIN, S., GODFREY, C. M., MACDONALD, M. T., LANGLOIS, E. V., SOARES-WEISER, K., MORIARTY, J., CLIFFORD, T., TUNCALP, O. & STRAUS, S. E. 2018. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Ann Intern Med*, 169, 467-473.
- TUCKER, J., MURPHY, E. M. A., STEEN, M. & CLIFTON, V. L. 2019. Understanding what impacts on disclosing anal incontinence for women when comparing bowel-screening tools: a phenomenological study. *BMC Women's Health*, 19, 142.
- TUFFORD, L. & NEWMAN, P. 2012. Bracketing in Qualitative Research. *Qualitative social work : QSW : research and practice*, 11, 80-96.
- TURNER, P. & TURNER, S. 2009. Triangulation in practice. *Virtual reality*, 13, 171-181.
- ULE, P. A. & IDEMUDIA, S. 2018. Knowledge Gap: The Magic behind Knowledge Expansion.
- UNIVERSITY OF PLYMOUTH 2018. Code of Good Research Practice.
- UZUN, A. K. 2020. An Overview of Toilet Training in Children. *Advances in Health Sciences Research*, 313.
- VAN DE SCHOOT, R., YERKES, M. A., MOUW, J. M. & SONNEVELD, H. 2013. What took them so long? Explaining PhD delays among doctoral candidates. *PloS one*, 8, e68839-e68839.
- VAN DER MEULEN, M., ZAMANIPoor NAJAFABADI, A. H., BROERSEN, L. H. A., SCHOONES, J. W., PEREIRA, A. M., VAN FURTH, W. R., CLAESSEN, K. M. J. A. & BIERMASZ, N. R. 2021. State of the Art of Patient-reported Outcomes in Acromegaly or GH Deficiency: A Systematic Review and Meta-analysis. *The Journal of Clinical Endocrinology & Metabolism*, dgab874.
- VAN NUNEN, K., KAERTS, N., WYNDAELE, J.-J., VERMANDEL, A. & HAL, G. V. 2015. Parents' views on toilet training (TT) A quantitative study to identify the beliefs and attitudes of parents concerning TT. *Journal of Child Health Care*, 19, 265-274.

- VAN VLIET, P., HUNTER, S. M., DONALDSON, C. & POMEROY, V. 2016. Using the TIDieR checklist to standardize the description of a functional strength training intervention for the upper limb after stroke. *Journal of Neurologic Physical Therapy*, 40, 203.
- VARPIO, L., PARADIS, E., UIJTDEHAAGE, S. & YOUNG, M. 2020. The distinctions between theory, theoretical framework, and conceptual framework. *Academic Medicine*, 95, 989-994.
- VASANT, D. H. & FORD, A. C. 2020. Functional gastrointestinal disorders in inflammatory bowel disease: Time for a paradigm shift? *World Journal of Gastroenterology*, 26, 3712.
- VERMANDEL, A., VAN KAMPEN, M., VAN GORP, C. & WYNDAELE, J. J. 2008. How to toilet train healthy children? A review of the literature. *Neurourology and urodynamics*, 27, 162-166.
- VRIJENS, D., BERGHMANS, B., NIEMAN, F., VAN OS, J., VAN KOEVERINGE, G. & LEUE, C. 2017. Prevalence of anxiety and depressive symptoms and their association with pelvic floor dysfunctions—A cross sectional cohort study at a Pelvic Care Centre. *Neurourology and Urodynamics*.
- WAGNER, E. H., GLASGOW, R. E., DAVIS, C., BONOMI, A. E., PROVOST, L., MCCULLOCH, D., CARVER, P. & SIXTA, C. 2001. Quality improvement in chronic illness care: a collaborative approach. *The Joint Commission journal on quality improvement*, 27, 63-80.
- WALLACE, S. L., TOROSIS, M. & ROGO-GUPTA, L. 2021. Does Rectocele on Defecography Equate to Rectocele on Physical Examination in Patients With Defecatory Symptoms? *Female pelvic medicine & reconstructive surgery*, 27, 18-22.
- WAN, T., JUN, H., HUI ZHANG, P. W. & HUA, H. 2015. Kappa coefficient: a popular measure of rater agreement. *Shanghai archives of psychiatry*, 27, 62.
- WATERFIELD, A., WATERFIELD, M., CAMPBELL, J. & FREEMAN, R. 2021. Can effective supervised pelvic floor muscle training be provided by primary care nurses? A randomized controlled trial. *International Urogynecology Journal*.
- WEI-CHENG LIU SONG-LIN WAN, S. M. Y. X.-H. R. C.-P. T. Z. D. K.-Y. Z. Y.-H. W. C.-Q. J. Q. Q. 2016. Transanal surgery for obstructed defecation syndrome: Literature review and a single-center experience. *World Journal of Gastroenterology*, 22, 7983-7998.
- WEIJTERS, B., CABOOTER, E. & SCHILLEWAERT, N. 2010. The effect of rating scale format on response styles: The number of response categories and response category labels. *International journal of research in marketing*, 27, 236-247.
- WELTENS, N., IVEN, J., VAN OUDENHOVE, L. & KANO, M. 2018. The gut-brain axis in health neuroscience: implications for functional gastrointestinal disorders and appetite regulation: The gut-brain axis in health neuroscience. *Annals of the New York Academy of Sciences*, 1428, 129-150.
- WEN, N.-R., HU, Y.-L., ZHAO, L., TUXUN, T., HUSAIYIN, A., SAILAI, Y., ABULIMITI, A., WANG, Y.-H. & YANG, P. 2014. Biofeedback-guided pelvic floor exercise therapy for obstructive defecation: an effective alternative. *World Journal of Gastroenterology: WJG*, 20, 9162.
- WETHERELL, M. 1998. Positioning and interpretative repertoires: Conversation analysis and post-structuralism in dialogue. *Discourse & society*, 9, 387-412.
- WILLIAMS, B. R., NODORA, J., NEWMAN, D. K., KANE LOW, L., JAMES, A. S., CAMENGA, D. R., HEBERT-BEIRNE, J., BRADY, S. S., HARDACKER, C. T., SMITH, A. L., CUNNINGHAM, S. D., BURGIO, K. L. & PREVENTION OF LOWER URINARY TRACT SYMPTOMS RESEARCH, C. 2020. I never knew anyone who peed on themselves on purpose: Exploring adolescent and adult women's lay language and discourse about bladder health and function. *Neurorol Urodyn*, 39, 225-236.
- WILLIAMS, D. M. & RHODES, R. E. 2016. The confounded self-efficacy construct: conceptual analysis and recommendations for future research. *Health psychology review*, 10, 113-128.
- WILSON, D. T., WALWYN, R. E. A., BROWN, J., FARRIN, A. J. & BROWN, S. R. 2015. Statistical challenges in assessing potential efficacy of complex interventions in pilot or feasibility studies. *Trials*, 16, O90.

- WINDGASSEN, S., MOSS-MORRIS, R., CHILCOT, J., SIBELLI, A., GOLDSMITH, K. & CHALDER, T. 2017. The journey between brain and gut: A systematic review of psychological mechanisms of treatment effect in irritable bowel syndrome. *Br J Health Psychol*, 22, 701-736.
- WITTKAMP, M. F., BERTSCH, K., VÖGELE, C. & SCHULZ, A. 2018. A latent state-trait analysis of interoceptive accuracy. *Psychophysiology*, 55, e13055-n/a.
- WOOLSON, R. 2007. Wilcoxon signed-rank test. *Wiley encyclopedia of clinical trials*, 1-3.
- WORLD HEALTH ORGANIZATION. 2017. *International Classification of Health Interventions (ICHI)* [Online]. Available: <https://www.who.int/classifications/ichi/en/> [Accessed 17.04.2020].
- WORTLEY, S., SEEPERSAD, R., MCALLA, A., SINGH, R., MANDON, N., GREENE, C., MYERS, N. & ROSWELL, T. 2008. Review of the roots of youth violence: Literature reviews. *Ministry of Children and Youth Services*.
- WRAY, N., MARKOVIC, M. & MANDERSON, L. 2007. "Researcher saturation": the impact of data triangulation and intensive-research practices on the researcher and qualitative research process. *Qualitative Health Research*, 17, 1392-1402.
- WU, H.-Y. 2010. Achieving urinary continence in children. *Nature Reviews Urology*, 7, 371-377.
- YANG, R., YUE, C., LI, J., ZHU, J., CHEN, H. & WEI, J. 2020. The Influence of Information Intervention Cognition on College Students' Energy-Saving Behavior Intentions. *International Journal of Environmental Research and Public Health*, 17, 1659.
- YANG, X., ZHANG, M., KONG, L., WANG, Q. & HONG, J.-C. 2021. The Effects of Scientific Self-efficacy and Cognitive Anxiety on Science Engagement with the "Question-Observation-Doing-Explanation" Model during School Disruption in COVID-19 Pandemic. *Journal of Science Education and Technology*, 30, 380-393.
- YANOS, P. T. & ZIEDONIS, D. M. 2006. The patient-oriented clinician-researcher: advantages and challenges of being a double agent. *Psychiatric services (Washington, D.C.)*, 57, 249-253.
- YEO, G. B. & NEAL, A. 2013. Revisiting the Functional Properties of Self-Efficacy: A Dynamic Perspective. *Journal of management*, 39, 1385-1396.
- ZENEBE, C. B., CHANIE, W. F., AREGAWI, A. B., ANDARGIE, T. M. & MIHRET, M. S. 2021. The effect of women's body mass index on pelvic organ prolapse: a systematic review and meta analysis. *Reproductive Health*, 18, 45.

## Appendix 1: Search strategies

Search	Query	Records retrieved
<b>Medline (Ovid)</b> search conducted on 21.05.2019	15 Medline ("obstructive defecation" OR "obstructive defaecation" OR rectocele).ti,ab	1231
	18 Medline(empt* ADJ1 (rectum OR rectal)).ti,ab	202
	40 MedlineRECTOCELE/	663
	41 Medline(15 OR 18 OR 40)	1589
	20 Medline(Pelvic OR Biofeedback OR "Rectal irrigation" OR Lavage OR Laxative* OR Suppositor* OR Enema* OR Electro-stimulation OR electrotherapy OR electrostimulation OR Digitat* OR Splint* OR Conservative OR Patient-centred OR Patient-centered).ti,ab	302027
		17042
	21 Medline "THERAPEUTIC IRRIGATION"/	6926
	22 Medline ENEMA/	19693
	23 Medline "ELECTRIC STIMULATION THERAPY"/	1755
	24 Medline "CONSERVATIVE TREATMENT"/	334284
25 Medline(20 OR 21 OR 22 OR 23 OR 24)	<b>903</b>	
42 Medline(41 AND 25)		
Limit from 1984 to present; language limits to English only		

Search	Query	Records retrieved
<b>EMBASE (Elsevier)</b> search conducted on 21.05.2019	5 (empt* ADJ2 (rectum OR rectal)).ti,ab	407
	6 ("obstructive defecation" OR "obstructive defaecation" OR rectocele).ti,ab	2333
	7 DEFAECATION DISORDER/ OR RECTOCELE/ (5 OR 6 OR 7)	4668
	9 (Pelvic OR Biofeedback OR "Rectal irrigation" OR Lavage OR Laxative* OR Suppositor* OR Enema* OR Electro-stimulation OR electrotherapy OR electrostimulation OR Digitat* OR Splint* OR Conservative OR Patient-centred OR Patient-centered).ti,ab	5511
	11 COLON LAVAGE SYSTEM/	12
	12 CONSERVATIVE TREATMENT/ OR ENEMA/ OR ELECTROSTIMULATION/	148470
	13 (9 OR 11 OR 12)	516000
	14 (8 AND 13)	2652
	<b>1976</b> (after duplicates removed)	
Limit from 1947 to present; language limits to English only		

Search	Query	Records retrieved
<b>PsycINFO (APA)</b> search conducted on 21.05.2019	44 ("obstructive defecation" OR "obstructive defaecation" OR rectocele).ti,ab	6
	45 DEFAECATION/	640
	46 (43 OR 44 OR 45)	648
	47 (Pelvic OR Biofeedback OR "Rectal irrigation" OR Lavage OR Laxative* OR Suppositor* OR Enema* OR Electro-stimulation OR electrotherapy OR electrostimulation OR Digitat* OR Splint* OR Conservative OR Patient-centred OR Patient-centered).ti,ab	24978
	48 BIOFEEDBACK TRAINING/	2583
	49 (47 OR 48)	25468
	50 (46 AND 49)	20
Limit from 1967 to present; language limits to English only		<b>14</b> (after duplicates removed)

Search	Query	Records retrieved
<b>CINAHL (EBSCO)</b> search conducted on 21.05.2019	27 ("obstructive defecation" OR "obstructive defaecation" OR rectocele).ti,ab	143
	28 (empt* ADJ2 (rectum OR rectal)).ti,ab	24
	36 RECTOCELE/	128
	37 (27 OR 28 OR 36)	231
	30 (Pelvic OR Biofeedback OR "Rectal irrigation" OR Lavage OR Laxative* OR Suppositor* OR Enema* OR Electro-stimulation OR electrotherapy OR electrostimulation OR Digitat* OR Splint* OR Conservative OR Patient-centred OR Patient-centered).ti,ab	60963
	32 BOWEL IRRIGATION (IOWA NIC)/	1
	33 ELECTRIC STIMULATION/	9595
	34 ENEMA/	975
	35 (30 OR 32 OR 33 OR 34)	70492
38 (37 AND 35)	140	
Limit from 1984 to present; language limits to English only		<b>25</b> (after duplicates removed)

Search	Query	Records retrieved
<b>Emcare (Ovid)</b> search conducted on 21.05.2019	51 (empt* ADJ2 (rectum OR rectal)).ti,ab	57
	52 ("obstructive defecation" OR "obstructive defaecation" OR rectocele).ti,ab	232
	53 DEFAECATION DISORDER/	548
	54 RECTOCELE/	423
	55 (51 OR 52 OR 53 OR 54)	990
	56 (Pelvic OR Biofeedback OR "Rectal irrigation" OR Lavage OR Laxative* OR Suppositor* OR Enema* OR Electro-stimulation OR electrotherapy OR electrostimulation OR Digitat* OR Splint* OR Conservative OR Patient-centred OR Patient-centered).ti,ab	87838
	57 ENEMA/	2152
	58 COLON LAVAGE/	368
	59 ELECTROSTIMULATION/	10852
	60 CONSERVATIVE TREATMENT/	27708
61 (56 OR 57 OR 58 OR 59 OR 60)	113782	
62 (55 AND 61)	464	
Limit from 2005 to present; language limits to English only		<b>30</b> (after duplicates removed)

Search	Query	Records retrieved
<b>AMED (Ovid)</b> search conducted on 21.05.2019	63 (empt* ADJ2 (rectum OR rectal)).ti,ab	0
	64 ("obstructive defecation" OR "obstructive defaecation" OR rectocele).ti,ab	0
	65 DEFAECATION/	<b>17</b>
Limit from 1985 to present; language limits to English only		

Search	Query	Records retrieved
<b>Web of Science (Thomson Reuters)</b> search conducted on 11.06.2019	4 #2 AND #1 Refined by: [excluding] WEB OF SCIENCE CATEGORIES: (SURGERY OR GASTROENTEROLOGY HEPATOLOGY OR UROLOGY NEPHROLOGY OR RADIOLOGY NUCLEAR MEDICINE MEDICAL IMAGING OR BIOTECHNOLOGY APPLIED MICROBIOLOGY OR ANESTHESIOLOGY OR RHEUMATOLOGY OR PEDIATRICS)	284
	3 #2 AND #1	961



	<p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years</p> <p>2 TS=(Pelvic OR Biofeedback OR "Rectal irrigation" OR Lavage OR Laxative* OR Suppositor* OR Enema* OR Electro-stimulation OR electrotherapy OR electrostimulation OR Digital*)</p> <p>Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years</p> <p>1 TS=("obstructive defaecation" OR "obstructive defaecation" OR rectocele) Indexes=SCI-EXPANDED, SSCI, A&amp;HCI, CPCI-S, CPCI-SSH, ESCI Timespan=All years</p>	<p>183537</p> <p>1459</p> <p><b>118</b> (after duplicates removed)</p>
Limit from 1997 to present; language limits to English only		

Search	Query	Records retrieved
<b>Scopus (Elsevier)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	<b>6</b>
Limit from 2004 to present; language limits to English only		

Search	Query	Records retrieved
<b>Prospero (NIHR)</b> search conducted on 05.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	<b>0</b>
Limit from 2011 to present; language limits to English only		

Search	Query	Records retrieved
<b>Open Grey (GreyNet International)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	<b>0</b>
Limit from 1992 to present; language limits to English only		

Search	Query	Records retrieved
<b>ClinicalTrials.gov (US National Library of Medicine)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	1
Limit from 2000 to present; language limits to English only		

Search	Query	Records retrieved
<b>International Clinical Trials Registry Platform Search Portal (WHO)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	0
Limit from 2004 to present; language limits to English only		

Search	Query	Records retrieved
<b>UK Clinical Trials Gateway (NHIR)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	0
Limit from 2006 to present; language limits to English only		

Search	Query	Records retrieved
<b>International Standard Randomised Controlled Trial Number Registry (ISRCTN)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	1
Limit from 2000 to present; language limits to English only		

Search	Query	Records retrieved
<b>JBI (University of Plymouth Portal)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	0
Limit from 2010 to present; language limits to English only		

Search	Query	Records retrieved
<b>Epistemonikos (Epistemonikos Foundation)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	0
Limit from 2009 to present; language limits to English only		

Search	Query	Records retrieved
<b>Cochrane Library (Wiley)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	<b>26</b>
Limit from 1996 to present; language limits to English only		

Search	Query	Records retrieved
<b>ProQuest Dissertations and Theses (ProQuest)</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	<b>0</b>
Limit to 1938 to present; language limits to English only		

Search	Query	Records retrieved
<b>MedNar</b> search conducted on 17.06.2019	Key words: rectocele; obstructive defecation; obstructive defaecation	<b>0</b>
Limit from 1972 to present; language limits to English only		

## Appendix 2: Studies ineligible following full-text review

#	Study	Reason for exclusion
1	Rao, S. S. C., Welcher, K. D., & Pelsang, R. E. (1997). Effects of biofeedback therapy on anorectal function in obstructive defecation. <i>Digestive Diseases and Sciences</i> , 42(11), 2197-2205.	Ineligible population: no gender outcome detail
2	Rao, S. S. C., Welcher, K. D., & Leistikow, J. S. (1998). Obstructive defecation: A failure of rectoanal coordination. <i>American Journal of Gastroenterology</i> , 93(7), 1042-1050.	Ineligible population: no gender outcome detail
3	Pucciani, F., Reggioli, M., & Ringressi, M. N. (2012). Obstructed defaecation: What is the role of rehabilitation? <i>Colorectal Disease</i> , 14(4), 474-479	Ineligible population: no gender outcome detail
4	Mazor, Y., Kellow, J. E., Prott, G. M., Jones, M. P., & Malcolm, A. (2019). Anorectal biofeedback: an effective therapy, but can we shorten the course to improve access to treatment? <i>Therapeutic advances in gastroenterology</i> , 12, 1756284819836072	Ineligible population: no gender outcome detail
5	Lau, C. W., Heymen, S., Alabaz, O., Iroatulam, A. J. N., & Wexner, S. D. (2000). Prognostic significance of rectocele, intussusception, and abnormal perineal descent in biofeedback treatment for constipated patients with paradoxical puborectalis contraction. <i>Diseases of the Colon and Rectum</i> , 43(4), 478-482.	Ineligible population: no gender outcome detail
6	Gosselink, M. P., Darby, M., Zimmerman, D., Smits, A., Van Kessel, I., Hop, W., . . . Schouten, W. (2005). Long-term follow-up of retrograde colonic irrigation for defaecation disturbances. <i>Colorectal Disease</i> , 7(1), 65-69.	Ineligible population: no gender outcome detail
7	Chan, D., Saklani, A., Shah, P., Lewis, M., & Haray, P. (2012). Rectal irrigation: a useful tool in the armamentarium for functional bowel disorders. <i>Colorectal Disease</i> , 14(6), 748-752.	Ineligible population: no gender outcome detail
8	Cadeddu F, Salis F, Ciangola CI, Milito G. Biofeedback and electrostimulation: Last chance or first choice for obstructed defecation? <i>Surgery (United States)</i> . 2015; 157(2):405-6.	Ineligible context: not enough detail was included in the article, which was an editorial letter only.
9	Wadhawan HaB, S. R. Role of multidisciplinary pelvic floor clinic in the management of complex pelvic floor disorders; a conservative approach may be appropriate. <i>Colorectal Dis</i> . 2009; 11:29.	Ineligible context: The paper does not have enough detail to address scoping review questions.
10	Yang J, Han J, Zhu F, Wang Y. Ring and Gellhorn pessaries used in patients with pelvic organ prolapse: a retrospective study of 8 years. <i>Arch Gynecol Obstet</i> . 2018; 298(3):623-9.	Ineligible context: The paper does not have enough detail to address scoping review questions.
11	Dailianas A, Skandalis N, Rimikis MN, Koutsomanis D, Kardasi M, Archimandritis A. Pelvic floor study in patients with obstructive defecation: Influence of biofeedback. <i>J Clin Gastroenterol</i> . 2000; 30(2):176-80.	Ineligible concept: a comparison study between three groups – Group A included 24 patients with obstructive defaecation, Group B, 25 patients with constipation, and Group C, 22 healthy controls and the evaluation of biofeedback treatment. Rectocele was excluded from Group A.

12	Pucciani F, Raggioli M, Ringressi M. Usefulness of psyllium in the rehabilitation of obstructed defecation. <i>Tech Coloproctol.</i> 2011; 15(4):377-83.	Ineligible concept: the study investigates psyllium, which is in the laxative family.
13	Resende A, Stuepp L, Bernardes B, Torelli L, Oliveira E, Castro R, <i>et al.</i> Pelvic organ prolapse symptoms: can exercises program improve it? <i>International Urogynecology Journal.</i> 2013; 24:S64-S.	Ineligible concept: did not meet scoping review questions. There is no specific mention of rectal emptying difficulties – only briefly mentions rectocele improvement and not as a symptom.
14	Cadeddu, F. S., P. Franceschilli, L. De Luca, E. Grande, M. Milito, G. (2012). Biofeedback therapy plus anal electrostimulation for the treatment of obstructed defecation. <i>Techniques in Coloproctology</i> , 16(1), 99.	Unable to obtain full-text paper: abstract only – author contacted
15	Fomenko, O., Titov, A., Belousova, S., & Egorova, D. (2017). The role of biofeedback therapy in functional disorders. Paper presented at the Neurogastroenterology and Motility.	Unable to obtain full-text paper: abstract only – author contacted
16	Aigner F, M. D., Mascher A, Maier H, Zweckberger A, Madersbacher H. (2011). Transanal irrigation - A promising strategy of conservative treatment for defaecation disorders; short- and medium-term results. <i>International Urogynecology Journal and Pelvic Floor Dysfunction</i> , 22.	Unable to obtain full-text paper: abstract only – author advised that publication could not be completed.
17	Bennett, R., Mongiu, A., Farmer, R., Abell, T., & Stocker, A. (2018). SACRAL NERVE STIMULATION FOR CONSTIPATION. Paper presented at the Diseases of the Colon & Rectum.	Unable to obtain full-text paper: abstract only – author contacted
18	Proctor, M. J. M., W. Collie, M. H. S. (2016). Sacral nerve stimulation to treat failure of defecation and constipation as an alternative to surgical intervention. <i>Colorectal Disease</i> , 18, 63.	Unable to obtain full-text paper: abstract only – author contacted
19	Giraud, D., Beccaria, N., & Lamberti, G. (2011). Pelvic floor muscle training, negative pressure abdominal exercise and pelvic organ prolapse symptoms: a randomized clinical trial. Paper presented at the Neurourology and Urodynamics.	Unable to obtain full-text paper: abstract only – author contacted
20	Byrne, S. G., T. McCaffrey, C. Molyneux, W. Baraza, A. Sharma, K. Telford. (2016). Is trans-anal rectal irrigation (TARI) an effective treatment for patients with severe anorectal dysfunction? <i>Colorectal Disease</i> , 18, 44.	Unable to obtain full-text paper: abstract only – author contacted
21	Haiying, C. D., H. P. Kamisan Atan, I. Caudwell-Hall, J. Guzman Rojas, R. (2014). Digitation associated with defecation: What does it mean in urogynecological patients? <i>Neurourology and Urodynamics</i> , 33(6), 882-883.	Unable to obtain full-text paper: abstract only – author contacted
22	Gurland, B. H. R. D. P., T. Hull, T. Zutshi, M. (2018). High doses of botox to treat levator spasm and obstructed defecation: To repeat or not. <i>Diseases of the Colon and Rectum</i> , 61(5).	Unable to obtain full-text paper: abstract only – author contacted
23	Courtice, S. C., M. Mohanlal, A. Ward, L. Weedon, N. Warwick, A. Gillespie, C. (2018). Dietetics is integral to the conservative management of functional defecatory disorders. <i>Colorectal Disease</i> , 20, 45	Unable to obtain full-text paper: abstract only – author contacted

24	Ron, Y. (2018). A randomized, open, placebo-controlled feasibility study to assess the value of specially designed toilet seat for patients suffering from obstructed defecation type of constipation. Paper presented at the Neurogastroenterology and Motility.	Unable to obtain full-text paper: abstract only – author contacted
25	Hagen S. A clinical trial to study the effects of traditional treatments in patients with pelvic organ prolapse. 2015 [cited Available from: <a href="https://clinicaltrials.gov/ct2/show/NCT01171846">https://clinicaltrials.gov/ct2/show/NCT01171846</a>	Unable to obtain full-text paper: no paper available (reported on clinical trials website)

## Appendix 3: Data extraction instrument

<b>Scoping review details</b>	
Scoping review title:	Identifying what health care initiated and self-initiated interventions are used by women for the management of rectal emptying difficulty secondary to obstructive defaecation: a scoping review
Review objective:	This scoping review aims to identify what interventions are used by women for the management of rectal emptying difficulty secondary to obstructive defaecation.
Review question:	What health care–initiated and self-initiated interventions are used by women for the management of rectal emptying difficulty secondary to ODS?
<b>Inclusion/exclusion criteria</b>	
Population	Adult female
Concept	Literature includes interventions such as digitation or splinting; or health care–initiated approaches such as suppositories, enemas, transanal irrigation, biofeedback, or electro-stimulation used by women to manage rectal emptying difficulty.
Context	Considers studies that focus on adult women (over the age of 18 years) living in their own homes in the community.
Types of study	Experimental and quasi-experimental study designs; analytical observational studies including prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies, and qualitative studies
<b>Study details and characteristics</b>	
Study citation details (e.g., author/s, date, title, journal, volume, issue, p.s)	
Country	
Type of study	
Type of paper	
Context	
Study inclusion criteria	
Study exclusion criteria	
Sample size (size/age/gender)	
Participants	
<b>Details/results extracted from the study</b> (in relation to the concept of the scoping review)	
<b>Health care initiated interventions</b>	
<b>Self-management interventions</b>	
<b>Follow-up</b>	



## Appendix 4: Characteristics of included studies

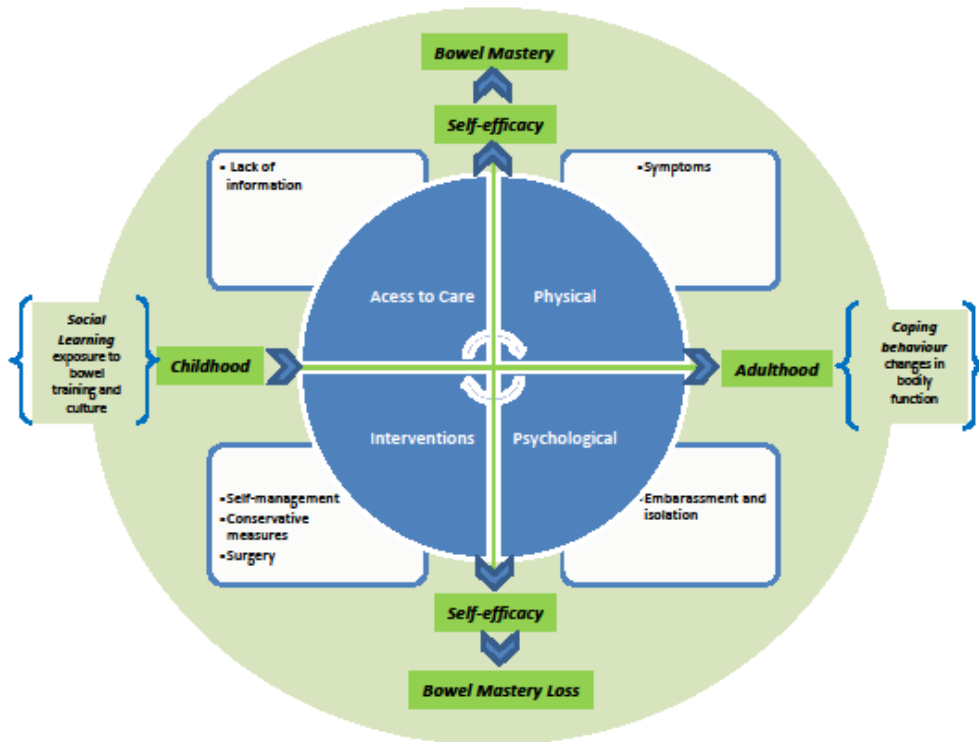
Study	Context	Intervention	Type of staff providing intervention	Participant characteristics	Groups	Outcomes measured	Description of main results
<p>Treatment of impaired defecation associated with rectocele by behavioral retraining (biofeedback)</p> <p>Mimura T, Roy AJ, Storrie JB, Kamm MA. 2000 (Mimura <i>et al.</i>, 2000)</p>	<p>Physiology Unit</p> <p>Determine the efficacy of biofeedback therapy</p>	Biofeedback	Biofeedback specialist nurse	<p>Impaired rectal evacuation with a rectocele greater than 2cm at proctography. The median size of the rectocele was 2.7cm (range, 2.1-5), barium trapping was seen in 20 patients (63%). Intrarectal intussusception in 12 patients (38%), perineal descent in 16 patients (50%), and enterocele in 12 patients (38%).</p>	32 women (median age, 52 years)	Bowel symptoms before and immediately after biofeedback and follow-up	<p>Three (12%) of the 25 patients had completely resolved their bowel issues at the follow-up. Twenty-two people (88%) said their symptoms had improved. The proportion of patients who had to strain, felt like their evacuation was incomplete, needed digital defaecation assistance, or needed to use an evacuant all dropped. None of these reductions, however, were statistically significant.</p>
<p>Management of patients with rectocele, multiple pelvic floor dysfunctions, and obstructed</p>	<p>Outpatient setting</p> <p>Efficacy of clinical management followed by biofeedback, and</p>	Biofeedback	No detail	<p>Pelvic floor dysfunction in the posterior compartment involving anal canal and inferior</p>	175 women (mean age = 54yrs; range 26-84) 103 met inclusion criteria	103 women received clinical treatment for three months; subsequently assigned to one of	<p>The constipation score improved in around half of the patients without surgery (clinical management alone = 33%; clinical management plus</p>

defecation syndrome  Murad-Regadas SM, Regadas FSP, Rodrigues LV, Fernandes GO da S, Buchen G, Kenmoti VT. 2012(Murad-Regadas <i>et al.</i> , 2012)	surgical treatment in patients with obstructed defecation, rectocele, and multiple dysfunctions evaluated with echodefecography.			rectum (including Grade I, II, and III rectocele, rectal intussusception, prolapse of the anal canal mucosa and anismus or non-relaxation) and in the middle compartment involving vagina and uterus (Grade III enterocele/sigmoidocele)		three treatment groups: Group 1 (n=34) exposed to clinical treatment only (fibre-rich diet (up to 30 g bran/day), liquid (up to 2 Litres/day) and bulk laxative for three months) Group II (n=14) continued with clinical treatment plus biofeedback (for those who did not respond to clinical treatment; twice a week for up to 10 sessions in the outpatient department) Group III (n=55) referred to surgical intervention – data not extracted for scoping review	biofeedback = 13.6%). In total, 48 women were assigned to Group I or II (clinical management with or without biofeedback) and 55 to surgery.
Biofeedback-guided pelvic floor exercise therapy for obstructive defecation: an effective alternative	General Surgical Department  Compare the quality-of-life scores of patients diagnosed with obstructive defecation (OD)	Biofeedback	Specialist researchers	Patients were assigned by computerised randomisation to BFT (n=44) or PEG (n=44) groups	88 consecutive patients: BFT group, median age = 54yr; and PEG group, median age = 57yr	BFT group had five-week manometric guided biofeedback training sessions lasting 30 min each. PEG group - oral polyethylene glycol treatment was administered; 17g	The Wexner Score data of the BFT group patients were considerably higher than the PEG group at each follow-up; 79.54% of BFT group patients resolved their constipation symptoms, compared to 20.45% of the PEG group

Wen N-R, Hu Y-L, Zhao L, Tuxun T, Husaiyin A, Sailai Y, <i>et al.</i> 2014(Wen <i>et al.</i> , 2014)	after biofeedback therapy (BFT) or oral polyethylene glycol (PEG) management.					of laxative with water x 3 daily over 14 days (+ high fibre diet)	patients. The BFT group's quality-of-life scores were enhanced. The BFT group's average quality of life score using the PACQOL questionnaire was 80.2.2 at the final follow-up time.
Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial  Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, <i>et al.</i> 2014(Hagen <i>et al.</i> , 2014)	Outpatient gynaecology clinics  Effectiveness of one-to-one individualised of a PFMT for reducing prolapse symptoms	Pelvic floor therapy	Women's health physiotherapists	New patients at outpatient gynaecology clinics with symptomatic prolapse at 25 centres (23 in the UK; one in Dunedin, New Zealand; and one in Sydney, Australia)	447 patients were randomised to the intervention group (n=225) or the control group (n=222); the mean age of participants was 56.8 years	Intervention group patients were invited to attend five one-to-one pelvic floor muscle training appointments over 16 weeks (at weeks 0, 2, 6, 11, and 16) with a women's health physiotherapist. An individualised home exercise programme was prescribed based on examination findings. Control group -patients with prolapse received lifestyle advice leaflet and no muscle training	At 6 and 12 months, women in the intervention group reported a larger improvement in prolapse symptoms (a significantly lower POP-SS) than those in the control group. After six months of muscle training, the intervention group had a lower prevalence of each specific prolapse symptom and bladder, bowel, and sexual problems, as well as a higher quality of life. Furthermore, at 6 and 12 months, women in the intervention group were more likely to indicate that their prolapse was improved.

<p>Outcomes of a comprehensive nonsurgical approach to pelvic floor rehabilitation for urinary symptoms, defecatory dysfunction (DD), and pelvic pain</p> <p>Starr JA, Drobnis EZ, Lenger S, Parrot J, Barrier B, Foster R. 2013(Starr <i>et al.</i>, 2013)</p>	<p>Outpatient setting</p> <p>Clinical efficacy of comprehensive pelvic floor rehab in women with symptoms of pelvic floor dysfunction</p>	<p>Pelvic floor therapy</p>	<p>Urogynaecology advanced practice nurses</p>	<p>Referred for pelvic floor therapy for patients with urinary, bowel, pelvic pain, and sexual symptoms over four years. 681 patients returned after the first session.</p>	<p>778 records of women over 18yrs Age range 18-95yrs; mean age = 51yrs</p>	<p>Five therapy sessions (one session every two weeks). Symptom questionnaires from the second visit to the final visit were completed.</p>	<p>In the three primary categories studied (urinary incontinence, defecatory dysfunction, and pelvic pain), the average symptom reduction was 80%; DD demonstrated considerable improvement at the second and third sessions, but not after that.</p>
---	---	-----------------------------	--	---	---	---	---

## Appendix 5: Concept Map



## **Appendix 6: Product Evaluation Questionnaire**

Women are commonly concerned about a heavy, dragging feeling in their genital area that can be caused by vaginal prolapse. There are different types of prolapse, such as bulging of the front wall of the vagina (cystocele), descent of the womb (uterus) or bulging of the back wall (rectocele). If the back wall is prolapsed, this can distort the position of the rectum (this holds the stool until ready to be passed) and therefore there may be difficulty in passing stool or a feeling that it has not emptied properly. To cope with this, some women will resort to using their fingers to apply pressure to the structures to aid passing their stool.

### **What is Femmeze?**

We have developed a new product to help women with this inconvenient and uncomfortable problem (bulging of the back wall, known as rectocele).

Essentially, the Femmeze product replaces the need to use fingers and is a simple design to help reposition the prolapse temporarily so that stool is passed more easily. The product can be reused following simple washing instructions.

### **Your help**

We are aiming to improve patient care for this condition, and therefore we are conducting an evaluation to understand how patients find using the Femmeze product compared to their own way of managing the condition.

We are also applying for the Femmeze product to be placed on prescription in order to increase its availability to women.

We would appreciate you completing this evaluation form and returning it in the envelope provided.

It is up to you to decide whether or not to take part. You are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the care you receive.

All information that is collected about you during the course of the evaluation will be kept strictly confidential.

**Thank you for taking time to be involved**

**Section 1 - About you**

Your age.....

How long have you had the rectocele (bulging of the vaginal back wall) condition? ..... Years .....Months

Have you been advised that your condition is suited to surgical correction?

Yes / No

Are you awaiting surgery? Yes / No

Have you decided against surgery? Yes / No

Have you had surgery that was not fully successful? Yes / No

How do you currently manage the condition?

Please tick any that apply:

- do nothing
- use my fingers (press inside or close to the vagina)
- use my fingers (inside my anus)
- use some other aid - please specify what

.....

Please offer any comments you may wish to about how you manage your condition, any impacts this has on your life

.....  
.....  
.....  
.....  
.....

**Section 2 - Current management approach**

**Please continue to manage the condition in your own chosen way for seven days, but in addition please keep a log of any observations you have about this:**

Day 1

.....  
.....

Day 2

.....  
.....

Day 3

.....  
.....

Day 4

.....  
.....

Day 5

.....  
.....

Day 6



.....  
.....  
Day 7  
.....  
.....

**Section 3 – Using the Femmeze**

The product package includes instructions for use:

***Please ensure that you have read and understood the instructions for use provided with the Femmeze***

Please keep a log of any observations during your use of the Femmeze:

Day 1  
.....  
.....

Day 2  
.....  
.....

Day 3  
.....  
.....

Day 4  
.....  
.....

Day 5  
.....  
.....

Day 6

.....  
.....

Day 7

.....  
.....

**Where did you use the Femmeze? (please tick)**

- Only when at home
- Anywhere I needed to - at home and at other places whilst out
- Only whilst out

**Section 4 - Your feedback**

**4.1 Preference**

Comparing your previous way of managing the condition, with using the Femmeze, which method did you prefer and why?

.....  
.....  
.....  
.....

**4.2 Effectiveness**

Regarding how well the Femmeze helps you to deal with your condition, how did you find it? (please circle)

very effective

useful

slightly helpful

not at all effective

Any comments?

.....  
.....  
.....

### **4.3 Ease of use**

Regarding how easy it was to use the Femmeze, how did you find it? (please circle)

very easy

easy

acceptable

difficult

very difficult

Any comments?

.....  
.....  
.....

### **4.4 Comfort**

If you chose to use Femmeze as a regular part of managing your condition, how comfortable was it? (tick all that apply)

Comfortable

Uncomfortable

I noticed bleeding

It was painful

Any comments?

.....

.....

.....

#### **4.5 Convenience, Storage and Carrying**

Please tell us if you found it convenient or not to keep Femmeze with you for when you wanted to use it: (please circle)

very convenient

convenient

acceptable

inconvenient

very inconvenient

Any comments?

.....

.....

.....

.....

#### **4.6 The 'feel' of Femmeze**

As a personal product for women to use to help manage their condition how does the product 'feel' to you? Please include in your comment's aspects such as the appearance, colour, carry case etc.

.....  
.....  
.....  
.....

**4.7 Availability on prescription**

Do you think the Femmeze should be available on prescription? Yes / No

Do you think you would use the Femmeze to help with your condition on a long-term basis?

Yes / No

Comment.....  
.....

**Finally, do you have any suggestions on how we could make this a better product?**

.....  
.....  
.....  
.....

**Thank you very much for your participation**

# Are you bothered by your bowel?

Are you having to help yourself  
empty?

If so, you aren't alone.....

We are looking for women to help us study a new device that may help to make life easier. If you are interested, please ask your consultant for more details.

Alternatively you can contact Sharon Eustice, Nurse Consultant at [sharoneustice@nhs.net](mailto:sharoneustice@nhs.net) or 01726 873095.

## **Appendix 8: Patient Information Leaflet**

### **PATIENT INFORMATION SHEET**

## **An intervention to improve the management of posterior vaginal compartment prolapse using Femmeze®: a feasibility study**

We would like you to consider this research study and then decide whether or not you wish to take part. Before you decide whether to participate or not it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to decide whether or not you wish to take part.

#### **What is Femmeze?**

We have developed a device to help women with the uncomfortable problem of bulging of the back wall in the vagina, known as rectocele (prolapse). The device replaces the need to use fingers and is a simple design to help reposition the prolapse temporarily so that stool is passed more easily from the rectum. If the back wall is prolapsed, this can distort the position of the rectum (this holds the stool until ready to be passed) and therefore there may be difficulty in passing stool or a feeling that it has not emptied properly. To cope with this, some women will resort to using their fingers to apply pressure to the structures to aid passing their stool.

The device is trademarked Femmeze® and is protected by Community Registered Design. It is made of an approved, non-toxic material. It is a hand-held angled device used vaginally. The device can be reused following simple washing instructions; and is registered as single-user item. It is supplied with

user instructions and a discrete carry case for hygiene and ease of use.



### **What is the purpose of this study?**

We are aiming to improve patient care for this condition and are conducting a study to understand how patients find using the Femmeze® device compared to their own way of managing the condition.

### **What is involved if you take part in the study?**

If you agree to take part, we will ask you to complete some questionnaires before and after using the Femmeze® device for eight weeks.

### **Do I have to take part?**

No, it is up to you to decide whether or not to take part. You can withdraw from the study at any time and without giving a reason without it having any effect on your medical treatment. If you would like to take part we will ask you to sign a consent form indicating your willingness to participate in the study. Any current or future healthcare that you receive will not be affected by deciding whether or not to take part in the study. Taking part in the study is voluntary.

### **What else is involved in the study?**

Your consultant will have arranged for you to have a proctogram, which is a usual part of your care. This will be performed in the Clinical Imaging Department. During the proctogram itself, we may ask you to use the Femmeze device during an additional x-ray imaging sequence so that we can see how best it works for you. The radiographer will provide you with the information relevant to the proctogram.

### **What will happen next?**

By the time you read this, you will have been referred to the Urogynaecology or Colorectal Department because of the symptoms and bother you are having



with a prolapse. Your consultant will have informed you about the study and asked for your permission to contact the lead investigator of the study, Sharon Eustice, Nurse Consultant. Sharon will make contact with you to discuss the study in further detail, where you can ask any questions, you need. She will ask if you would like to take part and if you say yes, Sharon will invite you to complete a consent form. Sharon will teach you how to use the Femmeze® device, give you questionnaires to complete before and after using the device. You will also be provided with your own Femmeze® to use, which you are welcome to keep once the study has finished.

Over an eight-week period, we would like you to use the Femmeze® instead of your usual way of managing your condition. After this time, Sharon will contact you again. However, Sharon will give you her contact details so that you can call her as you need during the eight weeks. Following this, Sharon will invite you to meet with her for an interview. The interview will be up to one hour long in a location of your choice. The purpose of the interview is to give you opportunity to speak about your experiences of living with the problem and being part of the study. We will treat your answers as confidential. We will not include your names or any other information that could identify you in any reports we write. We will destroy the notes and audiotapes after we complete our study and publish the results. At any time during this period, if you want to withdraw from the study, you are free to do so.

### **Expenses and payments**

If you are eligible for travel expenses as part of your usual visits to the hospital, this should be requested in the usual way.

### **What are the possible benefits of taking part?**

You will be treated by the doctors in the hospital in the usual way. By taking part in this study, you may benefit from using the Femmeze® device, which might improve your quality of life. Also, the information we get from this study will help improve future management of prolapse.

The standard pathway for helping women with difficulty emptying their rectum of stool currently consists of using suppositories, enemas or rectal irrigation. Femmeze will offer another choice for women.

### **What are the possible risks of taking part?**

The proctogram, which is part of standard care, involves the use of x-ray radiation. Exposure to radiation increases the risk of developing a cancer in later life.

We may ask you to use the Femmeze device during an x-ray imaging sequence which is additional to standard care, so that we can see how best it works for you. This may add up to 20% to the x-ray exposure used in the examination. This extra exposure is equivalent to less than six months of exposure to naturally occurring background radiation.

The potential for harm with inserting Femmeze is low. However, it is recognised that it may not help your symptoms, or you may feel it makes them worse. You are encouraged to stop using Femmeze at any time. Should the Femmeze® cause any discomfort or you do not want to continue using it at any time during the eight weeks, we ask that you inform Sharon Eustice (01726 873095 or email [sharoneustice@nhs.net](mailto:sharoneustice@nhs.net)). You are free to withdraw from the study at any time if you have any concerns.

### **Will my taking part be kept confidential?**

Yes, we will keep your records confidential and any data we collect will be anonymised. All patient information is stored on password protected NHS computer databases and in locked cabinets; and will only be accessible to the research team. Your data will be allocated a unique identification number.

### **What if there is a problem?**

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Patient Advisory Liaison Service on X or Sharon Eustice, Nurse Consultant on 01726 873095 or by email on [sharoneustice@nhs.net](mailto:sharoneustice@nhs.net)

**Will my GP be informed of my involvement in the study?**

Yes. We will send your GP a brief letter informing them of your participation in the study.

**How will the information I provide be used?**

We plan to publish the results in a health journal so others can read about and learn from the results of the study. The results may also be shared at scientific conferences

**Thank you for reading this.**

**If you have any questions or would like any more information, please contact**

**Sharon Eustice 01726 873095**

**Or email [sharoneustice@nhs.net](mailto:sharoneustice@nhs.net)**

**Please keep this information sheet for your records.**

**If you agree to enter the study, please sign the attached consent form and we will return a copy to you.**

## Appendix 9: Consent Form

Study Number:

Patient Identification Number for this trial:

### CONSENT FORM

Title of Project: *An intervention to improve the management of posterior vaginal compartment prolapse using Femmeze®: a feasibility study*

Name of Researcher: Sharon Eustice, Nurse Consultant

*Please initial box*

1. I confirm that I have read and understand the information sheet dated   
..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
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 X and X, from regulatory authorities or from the NHS 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 take part in the above study.

**Name of Patient, Date, Signature and Initial**

.....

**Name of Person, Date and Signature taking consent**

.....

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

## Appendix 10: Patient-centred device user guide

A demonstration/instructional video of how to use the Femmeze is available to view on the MDTi website at <https://www.mdti.co.uk/femmeze>

Instructions for Use are available on the MDTi website at <https://www.mdti.co.uk/femmeze> for the following languages:

Francaise (French)  
Deutsche (German)  
Italiana (Italian)  
Espanola (Spanish)  
Nederlands (Dutch)  
Suomalainen (Finnish)



The Kace Building,  
Victoria Passage,  
Wolverhampton,  
WV1 4LG,  
United Kingdom  
Company Reg No: 04383577  
Vat No: 836 8531 02  
[www.mdti.co.uk](http://www.mdti.co.uk) email: [info@mdti.co.uk](mailto:info@mdti.co.uk)  
Tel: +44 (0) 1902 778380 Fax: +44 (0) 1902 421360



### 5. TECHNICAL SPECIFICATIONS

The FEMMEZE® pack contains:  
1 x FEMMEZE® device  
2 x Sachet of lubricant  
1 x Instruction for use  
1 x Carrying pouch

Conformity	MDR 2017/745 Classification Class 1R Vagina Trainer
Autoclave cycles	100
Material Specification	Ticona Hostaform C9021 – POM Copolymer (ACETAL) Colour Pink BPA Free
Size and length of FEMMEZE® trainer	17cm x 8cm x 2.5cm
Pack dimension and weight	19cm x 12cm x 3cm 100 grams
Recommended that the product be replaced every:	5 years
Manufacturer's standard approvals:	13485:2016

### UK Help

MDTi care +44 (0)1902 778380

Monday - Friday, 9.00am to 5.00pm.  
An answer phone will be available out of these hours.  
Any queries or concerns about using the FEMMEZE® call MDTi Care. Calls are charged at the UK normal rate. For all web enquires please visit: [www.mdti.co.uk](http://www.mdti.co.uk).

### 6. BIBLIOGRAPHY

- Hagen, S., & Stark, D. (2011). Conservative prevention and management of pelvic organ prolapse in women. The Cochrane Library.
- Mustain, W. C. (2017). Approaches and Treatment of Intussusception, Volvulus, Rectal Prolapse, and Functional Disorders of the Colon, Rectum, and Anus: Functional Disorders: Rectocele. Clinics in colon and rectal surgery, 30(1), 63.
- Hai-Ying, C., Rojas, R. G., Hall, J. C., Atan, I. K., & Dietz, H. P. (2016). Digitation associated with defecation: what does it mean in urogynaecological patients?. International urogynaecology journal, 27(2), 229-232.



[www.mdti.co.uk](http://www.mdti.co.uk)

# FEMMEZE®

*improving dignity and self-management for women with pelvic organ prolapse (Rectocele)*  
Product code : 40075



## User Instructions

Additional languages available, please see back of leaflet

Version 2.7 March 2021

MDTi Careline: 01902 778380

For any queries about using your Femmeze® please call **Monday-Friday, 9.00am to 5.00pm.**  
An answer-phone will be available out of these hours. Calls are charged.

Please read carefully before using.  
Always follow instructions before use.

## CONTENTS

1. Instructions for use.
2. Inserting your FEMMEZE® trainer.
3. Caring for your FEMMEZE® trainer.
- 3a. Cleaning instructions.
4. Other Information.
5. Technical Specifications.
6. Bibliography.

Indications of Use: The Femmeze Rectocele Device is for use as a manual, reusable and removable device placed into the vagina temporarily to re-align the rectum tissue to treat a rectocele. The device is used to **replace the use of pessaries or fingers.**

### The FEMMEZE®

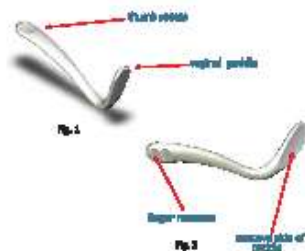
Where there is bulging of the back wall (rectocele), this can distort the position of the rectum and therefore **there may be difficulty in passing stool. The rectum wall bulges into the vagina. To cope with this, some women will resort to inserting their fingers into the vagina to apply pressure to the vaginal wall, repositioning the rectocele to aid passing their stool. The rectocele bulges into the vagina causing narrowing and can cause a colic etc which can be temporarily repositioned** using the FEMMEZE®.

### 1. INSTRUCTIONS FOR USE

The FEMMEZE® has been designed to be safe, easy and convenient to use whilst being able to be stored in a discreet and easily manageable pouch, which also includes space for small sachets or 50ml tube of lubricant to be accommodated.

The FEMMEZE® may be used as part of the care and self-treatment of women who are experiencing a rectocele. Rectocele (pelvic organ prolapse) is a distressing long-term condition. The rectum herniates forward through a vaginal tissue-wall tear, obstructing bowel emptying. The condition can typically be attributed to childbirth or hysterectomy.

The FEMMEZE® is shaped like a shodhorn, the paddle end of the device is inserted into the vagina whilst your thumb rests within the recess that is located at the top of the handle (Fig. 1) and with at least two fingers located within the grooves that are positioned on the reverse of the handle (Fig. 2).



**This leaflet offers advice on the use and care of your FEMMEZE®.** The device is a single-user device and must only be used by you.

**IMPORTANT: Never attempt to insert the FEMMEZE® using a gripped hand around the handle of the device as this may result in you applying a greater pressure than that which is required in order to use the device safely and effectively.**

**IMPORTANT: These instructions are intended as a guide and you should seek the advice of your doctor or nurse specialist before using this device.**

### 2. INSERTING YOUR FEMMEZE®

In order to re-align the rectum the FEMMEZE® is **recommended for use rather than your fingers.**

**If using the device for the first time,** wash it thoroughly in hot soapy water then rinse and dry it to remove all traces of soap (to avoid possible irritation).

To insert the device apply a small amount of a vaginal lubricant around the paddle of the device, gently insert into the vagina as shown in Diagram 1; push in a posterior direction repositioning the rectocele so as to permit emptying as in Diagram 2.

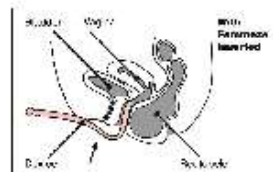


Diagram 2

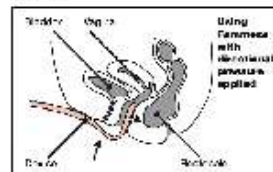


Diagram 3

### 3. CARING FOR YOUR FEMMEZE®

You should check your device before it is used for any cracks or rough edges. If there is any damage to the device then it is important that you do not use and should immediately contact the manufacturer for a replacement by calling the Careline number +44 (0) 1902 778380 or email info@mdt.co.uk.

### 3a. CLEANING INSTRUCTIONS

This device is supplied as **sterile**. It is to be cleaned thoroughly all over with warm soapy water and then dried off before use or thoroughly wiped over with a sterile wipe. Before and after each use of the device ensure that you repeat the cleaning instructions. The device can also be cleaned in boiling hot water before use (allow the water to cool before removing). **Do not use a disinfectant.**

### 4. OTHER INFORMATION

**IMPORTANT: This device has been designed to be used for inserting into the vagina, it should never be inserted into the rectum.**

The FEMMEZE® should only be used on yourself, by yourself. No other person such as a carer or partner should assist you with its use as they may apply excessive force on the device which may cause you harm.

#### Contra-Indications

Stop using the device immediately if you experience any of the following:

- Unexplained bleeding
- Pain or discomfort during use, or if
- You are unable to insert it into the vagina

If you experience any of the above you should discontinue use of the device and seek medical advice.

Caution: If you are pregnant or you think you are pregnant, we cannot advise use of the Femmeze.

**To use the Femmeze in the first few weeks following childbirth,** we recommend that you consult with your healthcare professional to check if you can use the Femmeze.

**IMPORTANT: Seek medical advice before using the device if the rectocele is visible outside the vagina or if you have any unresolved contraction of the vagina, such as may arise from pelvic radiotherapy.**

## Appendix 11: Bowel diary

This diary is designed to give us a good idea of your bowel habits. Please fill in the chart every day for 7 days (referring to the Bristol Stool Form Scale).

Date	Time	Type of stool (use number from Bristol stool chart)	Sense of incomplete emptying?	Feeling of being blocked?	Soiling?	Laxative taken (name and dose):

## The Bristol Stool Form Scale

Type 1



Separate hard lumps,  
like nuts (hard to pass)

Type 2



Sausage-shaped  
but lumpy

Type 3



Like a sausage but with  
cracks on its surface

Type 4



Like a sausage or snake,  
smooth and soft

Type 5



Soft blobs with clear-cut  
edges (passed easily)

Type 6



Fluffy pieces with ragged  
edges, a mushy stool

Type 7



Watery, no solid pieces  
ENTIRELY LIQUID



## **Appendix 12: Device Feedback Questionnaire**

### **Device Feedback Questionnaire**

Women are commonly concerned about a heavy, dragging feeling in their genital area that can be caused by vaginal prolapse. There are different types of prolapse, such as bulging of the front wall of the vagina (cystocele), descent of the womb (uterus) or bulging of the back wall (rectocele). If the back wall is prolapsed, this can distort the position of the rectum (this holds the stool until ready to be passed) and therefore there may be difficulty in passing stool or a feeling that it has not emptied properly. To cope with this, some women will resort to using their fingers to apply pressure to the structures to aid passing their stool.

#### **What is Femmeze®?**

We have developed a new product to help women with this inconvenient and uncomfortable problem (bulging of the back wall, known as rectocele).

Essentially, the Femmeze® product replaces the need to use fingers and is a simple design to help reposition the prolapse temporarily so that stool is passed more easily. The product can be reused following simple washing instructions.

#### **Your help**

We are aiming to improve patient care for this condition, and therefore we are conducting an evaluation to understand how patients find using the Femmeze® product compared to their own way of managing the condition.

We would appreciate you completing this evaluation form and returning it in the envelope provided.

It is up to you to decide whether or not to take part. You are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the care you receive.

All information that is collected about you during the course of the research will be kept strictly confide

**Thank you for taking time to be involved**

**Section 1 - About you**

Your age.....

How long have you had the rectocele (bulging of the vaginal back wall) condition? ..... Years .....Months

Have you been advised that your condition is suited to surgical correction?  
Yes / No

Are you awaiting surgery? Yes / No

Have you decided against surgery? Yes / No

Have you had surgery that was not fully successful? Yes / No

Prior to the study how did you manage the condition?  
Please tick any that apply:

- do nothing
- use my fingers
- use some other aid - please specify what

.....

Please offer any information you may wish to about how you manage your condition and any impact this has on your life:

.....  
.....  
.....

.....  
.....  
.....

**Section 2 – Using the Femmeze® device**

The product package includes instructions for use:

***Please ensure that you have read and understood the instructions for use provided with the Femmeze®***

Please keep a log of any observations during your use of the Femmeze®:

Week 1

.....  
.....  
.....

Week 2

.....  
.....  
.....

Week 3

.....  
.....  
.....

Week 4

.....  
.....  
.....

Week 5

.....  
.....  
.....  
Week 6

.....  
.....  
.....  
Week 7

.....  
.....  
.....  
Week 8

Where did you use the Femmeze®? (please tick)

- Only when at home
- Anywhere I needed to - at home and at other places whilst out
- Only whilst out

**Section 3 - Your feedback**

**Preference**

Comparing your previous way of managing the condition, with using the Femmeze®, which method do you prefer and why?

.....  
.....

.....  
.....  
.....

**Effectiveness**

Regarding how well the Femmeze® helps you to deal with your condition, how did you find it? (please circle)

very effective

useful

slightly helpful

not at all effective

If not effective for you, please tell us why?

.....  
.....  
.....  
.....  
.....

**Ease of use**

Regarding how easy it was to use the Femmeze®, how did you find it? (please circle)

very easy

easy

acceptable

difficult

very difficult

If it was difficult to use, please tell us why?

.....  
.....  
.....  
.....  
.....

**Place of use**

If you chose to use Femmeze® as a regular part of managing your condition,  
where did you use it?

- Only when at home
- Anywhere I needed to - at home and at other places whilst out
- Only whilst out

Please tell us why you made that choice?

.....  
.....  
.....  
.....  
.....

**Convenience**

Please tell us how convenient it was keep Femmeze® with you for when you  
wanted to use it: (please circle)

very convenient

convenient

acceptable

inconvenient

very inconvenient

If inconvenient, please tell us why?

.....  
.....  
.....  
.....  
.....

**The 'feel' of Femmeze®**

As a personal device for women to use to help manage their condition how does it 'feel' to you?

.....  
.....  
.....  
.....  
.....

**Finally, do you have any suggestions on how we could make this a better device?**

.....  
.....  
.....

.....  
.....

**Thank you very much for your participation**



## Appendix 13: Participant Guidance Note

<b>Study Number:</b>	162694
----------------------	--------

<b>Study Title:</b>	FEMMEZE
---------------------	---------

<b>Site ID:</b>	
-----------------	--

*Thank you for your help with the study. Here is some guidance on completing your questionnaires:*

### **Baseline (before you start using Femmeze)**

#### **Please complete the pink p.s:**

- Vaginal Symptoms Questionnaire
- Bowel diary
- Obstructed defaecation syndrome questionnaire

### **Week 1 – 8 (using Femmeze)**

- Device Feedback Questionnaire

### **Week 4 - 8 (using Femmeze)**

#### **Please complete the white p.s**

- Vaginal Symptoms Questionnaire
- Bowel diary
- Obstructed defaecation syndrome questionnaire
- PGI-I Scale

## Appendix 14: Interview schedule

### Interview Schedule

#### An intervention to improve the management of posterior vaginal compartment prolapse using Femmeze®: a feasibility study

<b>Pre-interview preparation</b>	The participant will be reassured on the following: <ul style="list-style-type: none"> <li>• Confidentiality</li> <li>• Interview is just between them and me</li> <li>• The location and time will be their choice</li> </ul>
<b>Introduction</b> (5 minutes)	Thank you for agreeing to meet with me. I am Sharon Eustice, Nurse Consultant and Chief Investigator for the Femmeze Study. I will record our conversation using this recording machine (show machine and obtain consent). I would like to talk with you about your experience of living with the problem. Also, I will ask you about how acceptable and practical Femmeze has been for you; and what might make it easier for more women to take part in the study. What we learn from today's conversation will help us understand how women cope; and improve the study and the Femmeze device for other women. Today I am with you as a researcher, so you can be as honest as you wish, I won't be offended by anything you say.  We will treat your answers as confidential. We will not include your names or any other information that could identify you in any reports we write. We will destroy the notes and audiotapes after we complete our study and publish the results.  <b>Do you have any questions about the study or the interview today?</b>
<b>Topic 1</b> (30 minutes) <b>Living with the problem</b>	<b>1. To begin, please tell me about your experience of living with difficulty with emptying due to your rectocele.</b> a. PROBE: How has this made you feel? <b>2. Did anything prevent you from seeking help early on?</b> a. PROBE: Why do you think women don't come forward for help?
	<i>Check that the participant is still comfortable to continue with the interview (and revisit as and when appropriate)</i>
<b>Topic 2</b> (10 minutes) <b>Using Femmeze</b>	<b>I would like to discuss your impressions of Femmeze.</b> <b>3. What words would you use to describe when using Femmeze for the first time?</b> <b>4. What words would you use to describe when using it regularly?</b> a. PROBE: How accessible is information about your problem? b. PROBE: Is the Femmeze packaging user friendly? <b>5. If you could design the perfect device for your problem, what would it look like?</b> <b>6. What issues might concern you about using Femmeze for a long time?</b>
<b>Topic 3</b> (10 minutes) <b>Being part of the study</b>	<b>I would like to seek your thoughts on being part of the study.</b> <b>7. Tell me about completing the questionnaires</b> a. PROBE: How can we make this easier for you? b. PROBE: Did you receive enough advice and information on completing them? <b>8. Do you have any thoughts on how we could we reach more women to recruit to the study?</b>
<b>Final thoughts</b> (5 minutes)	<b>Is there anything else you'd like to tell me?</b>  Thank you for your time

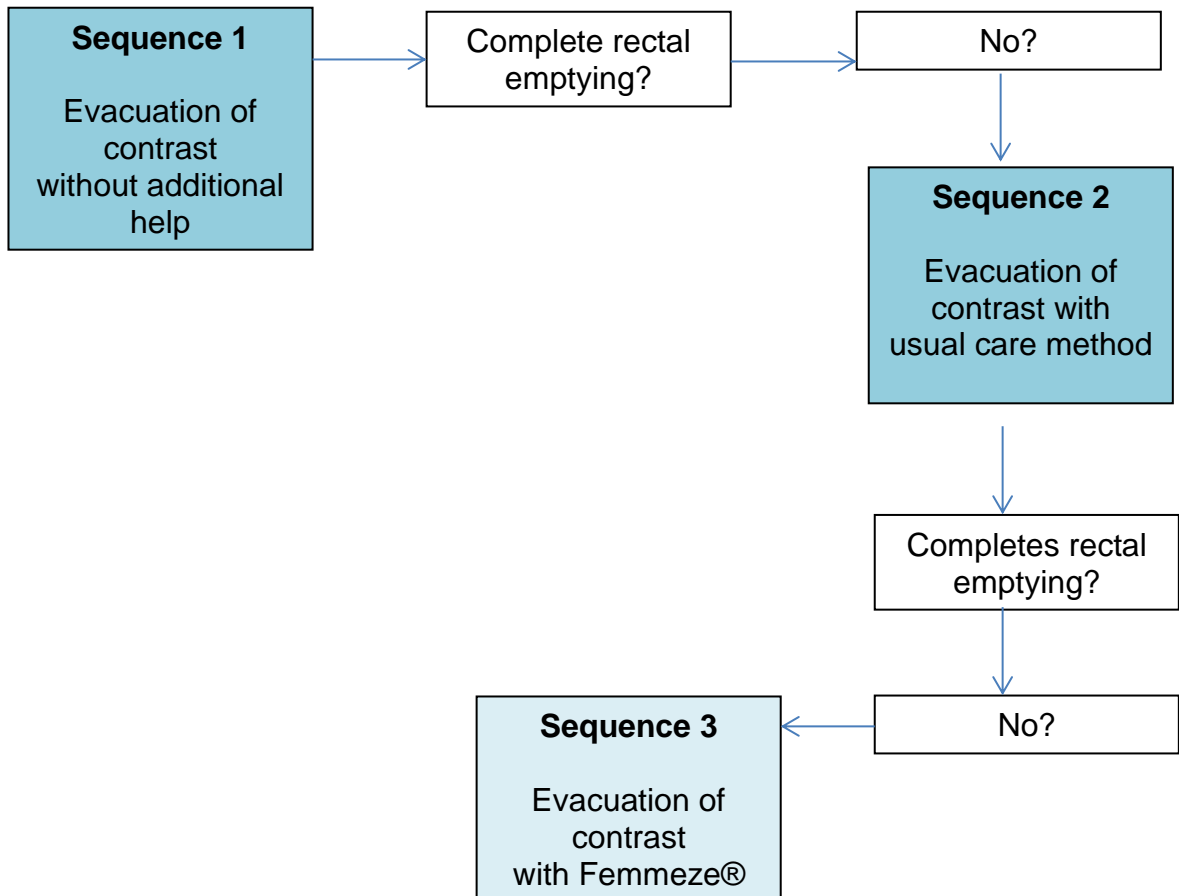
Adapted from: Harrell, Margaret C. and Melissa A. Bradley. Data Collection Methods: Semi-Structured Interviews and Focus Groups. Santa Monica, CA: RAND Corporation, 2009.  
[http://www.rand.org/pubs/technical\\_reports/TR718.html](http://www.rand.org/pubs/technical_reports/TR718.html)

Version 1: 24.08.16

## Appendix 15: Proctogram Measurements

### Proctogram measurements:

- a) What is the anatomical defect?
- b) Does the Femmeze® reduce rectal contrast?



## Appendix 16: Constipation standard pathway

### General points

- Consider constipation in those who have experienced at least 2 of the following symptoms over the preceding 3 months\*:
    - Fewer than 3 bowel movements per week
    - Straining
    - Lumpy or hard stools
    - Sensation of anorectal obstruction
    - Sensation of incomplete defaecation
    - Manual manoeuvring required to defecate
- \* Rome III Criteria
- In the majority of cases constipation **can** be confidently diagnosed and treated in primary care.

### Step-wise treatment in primary care:

1. adjust the dose of any constipating medications used for an underlying condition, if possible
2. explore lifestyle changes and non-pharmacological interventions, for example, regular toileting after breakfast (sit for up to 10 minutes) with feet supported on a footstool
3. prescribe laxatives and other medications appropriately to relieve symptoms if needed
4. suppositories or enemas (in addition to laxatives) if difficulty emptying the rectum
5. rectal irrigation with appropriate training
6. refer to Bladder and Bowel Specialist Service:
  - a. symptoms not responding to above treatment
  - b. rectal irrigation training
7. referral to secondary care for complex refractory cases may need specialist input for investigations such as colonoscopy or anal manometry.

### Please refer to secondary care:

Symptoms suspicious of colorectal cancer; include any of those listed below combined with a possible mass on rectal or abdominal examination:

- Recent alterations in bowel habit (over a number of weeks)
- Altered blood in the stool (as opposed to bright red blood on toilet paper)
- Recent weight loss
- Symptoms and signs of anaemia.

(Poston *et al.*, 2011)

## Appendix 17: Evaluation form findings

	Case 1	Case 2	Case 3	Case 4 (from letter)	Case 5	Case 6	Case 7	Case 8	Case 9
<b>Usual care comments</b>	Loads of backache; had to take laxatives; feels like I have an egg stuck in my vagina	Needed to push my perineum	Using my fingers has not been effective; feels like I'm trying to give birth – have to push so hard – go dizzy	Tried various ideas but nothing was very successful; excessive laxatives every day; depression set in; I was thinking an operation would be the only way out	Each day was unpredictable with discomfort on several days with bloating	It makes me extremely depressed because I am always in pain with spasms; causes me great anxiety and leads to constant diminishing social contact; I have to 'empty' first manually and second using a water/saline enema; makes me tired, lethargic and depressed	Used fingers with glove	Struggle everyday with this condition – ruining my life really; bowel movements with difficulty; having to press on perineum	Avoid constipation and don't trampoline!
<b>Using Femmeze comments</b>	As usual care	Good evacuation; tummy ache afterwards (in first use); used it today, needed to push perineum also – no tummy ache	Has made an unbelievable difference; don't feel like I am trying to give birth; when I use Femmeze I can hear a whooshing noise and then I go easily; it has drastically changed my life; I can't believe something so	I am so impressed that such a neat unobtrusive design has worked so well; I now only take one Movicol sachet a day and normal functioning occurs every morning	Initially I felt a bit uncertain about holding the Femmeze at the right angle but soon got used to it	Slightly painful to use, but need to practice; slightly better on day 2, but didn't help evacuate at as much; slight improvement on Day 3; changing diet and eating more fibre; much easier on Day 5; got the knack of using it now, I like it and take it out	I was not sure if I had cleared everything out – so felt uncomfortable, still used fingers	Wee bit sore at first use; think it will take a bit of getting used to; getting easier to use; bowel movement without strain; this is a good wee gadget; glad I have tried it out – like second nature	Have used Femmeze and whilst it seems to reduce the frequency I need to push it back

			simple is so effective			just in case I might need it			
<b>Preference between usual care or Femmeze</b>	Femmeze	No advantage over my usual care; may be more beneficial for women with a more severe rectocele	Femmeze	Femmeze	Femmeze	At the moment, I am still more successful in totally emptying when using my finger and enema; Femmeze did push out a lot of unwanted air enabling the stool to be further down the rectum	Fingers – I can feel how blocked the bowel is	Femmeze	No response

	<b>Case 1</b>	<b>Case 2</b>	<b>Case 3</b>	<b>Case 5</b>	<b>Case 6</b>	<b>Case 7</b>	<b>Case 8</b>	<b>Case 9</b>
<b>Effectiveness</b> <i>(Very effective, useful, slightly helpful, not at all effective)</i>	Useful (If you are overweight, it's harder to use)	Useful (it would definitely be something I'd continue to use occasionally, but not something I would rely on)	Very effective (it has changed my life)	Very effective (felt comfortable and gave me more confidence)	Slightly helpful (helped more stool along rectum but in the actual emptying of poop)	Not at all effective (felt I did not have the same feeling or control)	Very effective (great wee gadget so glad I gave it a try)	Very effective (a good product; requires time to use it and takes fractionally longer than a finger)
<b>Ease of use</b> <i>(Very easy, easy, acceptable, difficult, very difficult)</i>	Very easy (Less personal)	Easy (physically it was easy to use; psychologically it didn't feel right putting something like that inside me)	Very easy (the design is brilliant and it is easy to insert)	Easy (designed to do the job and gets away from trying other ways which can be extremely awkward)	Easy (the femmeze is simply in and gently push – no problem – compared to using finger up the bum – it's simple)	Acceptable (not unpleasant but do not get the same feeling as you do when using fingers)	Easy	Very easy
<b>Place of use</b> <i>(only when at home, anywhere I needed to, only at other places whilst out)</i>	Only when at home (work outdoors no way of carrying it; would prefer my own toilet)	Anywhere I needed to	Anywhere I needed to (why struggle so much when the Femmeze is so effective and so portable – fits in handbag easily)	Only when at home (I would prefer to wash the device before and after use)	Anywhere I needed to (I'm ok using it ... as long as I have privacy and washing facilities I will continue to use my Femmeze)	Only when at home (would find it hard to wash when out other than using disabled toilets)	Only when at home	Only when at home
<b>Convenience, storage and carrying</b> <i>(very convenient, convenient, acceptable, inconvenient, very inconvenient)</i>	Very convenient (nice handy bag to keep in bathroom – nobody knows what it is)	Convenient (it was in my handbag for a while before I began to use it; I don't think it would have been obvious what it was for if it fell into the wrong hands)	Very convenient (the carry case makes it so discreet)	No response (It would be fine if I did carry it around with me)	Very convenient (I keep it... in my handbag)	Inconvenient (but I will keep trying to see if I can get used to it)	Very convenient (nice wee pouch to keep it discreet)	Inconvenient
<b>'Feel' of Femmeze</b>	Feels fine; case and colour fine; no issues		Everything about it is perfect; well done	Important to use a lubricant; the case is excellent and a good idea to have somewhere to keep it out of sight	Feels ok; thought it looked strange; it's colour is great and the carry case pretty; but too big and	No response	Trying something different is always a challenge but the more you use it the easier it becomes –	Ok

					bulky for my handbag		nice feminine colour and wee velvet pouch nice touch	
<b>Suggestions made by the women</b>		Did it need to be quite so solid? Could it be made like a shoe-horn (thinner, bendier plastic)?	Just wish I was advised about it before	Perhaps ½ inch shorter on the handle end; the handle often knocks into the front of the toilet seat (it may be smaller than other toilet seats); I'm sure this will transform and improve a lot of women's lives with what is such an embarrassing and difficult problem	A smaller case like a spectacles sleeve; it is an excellent device	None	Advertising would make women more aware of what is available to help them out there	None



## Appendix 18: Framework Matrix of themes, categories and codes

Theme	Category	Code
Knowledge	Communication and information	Raising awareness
	Metacognitive knowledge	Knowledge of self
		Perception of self
	Factual knowledge	Toileting experience Seeking understanding
Consequences	External locus of control	Bullying and abuse
		Gender
		Impact of childbirth
		Impact on working
	Internal locus of control	Aging
		Inconvenience
		Intimacy with others
		Lack of control
		Skin health
		Social Isolation
Time constraint		
Finding a solution	Diagnostics	Having investigations
	Interventions	Patient-centred device
		Using fingers
Surgery	Waiting for help	
Psychological impact		Embarrassment
	Emotional factors	Fear
		Feeling alone
		Feeling angry
		Feeling anxious
		Feeling depressed
		Feeling distressed
		Feeling helpless
	Feeling like a burden	
		Frustration
	Self-esteem	
	Validation	
Coping	Tolerance	Being part of life
		Getting on with it
		Secrecy and stiff upper lip - coping
	Mastering	Sharing
	Internal factors	Feeling blocked
		Feeling of something coming out
		Feeling relief
		Pain

Physical impact		Mechanical impact
	External factors	Hygiene
		Toilets

## Appendix 19: Extract from the Framework Matrix

Theme	Category	Code	Data extracts
Knowledge	Communication and information	Raising awareness	<p>"I came across it just by chance that but could use my thumb I didn't know that's what other people had to do so it would be good if there was more information out there are other people out there that have to do this sort of thing and it just doesn't make you feel like dirty or you're the only one" (File 29; Reference 11)</p> <p>"There's nothing out there talking about this but even if you go into your doctors surgery you sit down and what do we do you know we said as we scan the walls and were looking and reading whatever information that's up there do you know even if there was a poster sort of saying are you experiencing bowel problems you know this could help it would insight maybe an interest that somebody could actually ask" (Participant 10; Reference 1)</p>
	Metacognitive knowledge	Knowledge of self	<p>"I think a lot of it is I've I know the um trying to think I know the function of it now and what it looks like and I know what goes where and I know how it comes out and now I've got that and I've got that picture and I've got the ways that I squeeze in this way and that way and I take my time it all makes sense and I sort of visualise it a little bit" (Participant 21; Reference 4)</p>
		Perception of self	<p>"the prolapse was very ugly and horrible when it protruded" (Participant 21; Reference 3)</p>
		Toileting experience	<p>"probably because I thought that bodily fluids and stuff like that it was just disgusting if you passed wind in our house it was like oh you had to the bathroom to do it they were very strict" (Participant 36; Reference 2)</p>
	Factual knowledge	Seeking understanding	<p>"the first time I heard the word digitation was when I had the proctogram and thought oh that's an easier way of understanding it" (Participant 22; Reference 1)</p>

