

ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

**Pelvic Floor Muscle Training for
Stress Urinary Incontinence,
Fecal Incontinence, and Pelvic
Organ Prolapse**

A Health Technology Assessment

AUGUST 2024

Key Messages

What Is This Health Technology Assessment About?

The pelvic floor is a funnel-shaped structure that has functions related to digestion, urination, and reproduction. The term *pelvic floor dysfunction* covers a variety of conditions, signs, and symptoms. The 3 most common conditions are stress urinary incontinence, fecal incontinence, and pelvic organ prolapse.

Conservative (nonmedication and nonsurgical) treatment for pelvic organ prolapse or stress urinary incontinence includes lifestyle and behavioural interventions, dietary modifications, and vaginal pessaries. For fecal incontinence, conservative treatment includes dietary modifications. Pelvic floor muscle training is another conservative treatment option.

This health technology assessment looked at how safe, effective, and cost-effective pelvic floor muscle training (supervised by a trained health care professional) is for adults with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse. It also looked at the budget impact of publicly funding pelvic floor muscle training and at the experiences, preferences, and values of people with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse.

What Did This Health Technology Assessment Find?

Pelvic floor muscle training likely improves symptoms and patient satisfaction for women with stress urinary incontinence or pelvic organ prolapse but yielded mixed results for symptom improvement for men with stress urinary incontinence after prostatectomy and little to no effect on symptom improvement for adults with fecal incontinence.

We estimate that publicly funding pelvic floor muscle training for adult women with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse would result in additional costs of \$185.3 million, \$275.6 million, and \$85.8 million, respectively, over the next 5 years. Publicly funding pelvic floor muscle training for men with stress urinary incontinence and fecal incontinence would result in additional costs of \$10.8 million and \$131.1 million, respectively, over the next 5 years.

People with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse felt that pelvic floor muscle training was an effective treatment option to manage their symptoms. However, lack of awareness of this treatment option, the cost of pelvic floor muscle training, and difficulty accessing pelvic floor muscle training services in some areas of the province were common barriers to treatment.

Acknowledgements

This report was developed by a multidisciplinary team from Ontario Health. The primary clinical epidemiologist was Kristen McMartin, the secondary clinical epidemiologist was Conrad Kabali, the primary medical librarian was Caroline Higgins, the secondary medical librarian was Corinne Holubowich, the primary health economist was Xuanqian Xie, the secondary health economist was Jennifer Guo, and the primary patient engagement analyst was Jigna Mistry.

The medical editor was Coren Walters-Stewart. Others involved in the development and production of this report were Emma Tolmie, Claude Soulodre, Susan Harrison, Sarah McDowell, Chunmei Li, Jigna Mistry, Andrée Mitchell, Charles de Mestral, and Nancy Sikich.

We would like to thank the following people and organizations for lending their expertise to the development of this report:

- Aisling Clancy, University of Ottawa
- Daniel Devere, Men’s Pelvic Floor Physiotherapy Clinic, Thornhill, Ontario
- Sinéad Dufour, McMaster University
- Nelly Faghani, Pelvic Health Solutions, Toronto
- Kate Jones, Kate Jones Pelvic Physiotherapy, Hamilton
- Melissa Northwood, McMaster University

We also thank our lived experience participants who generously gave their time to share their stories with us for this report.

The statements, conclusions, and views expressed in this report do not necessarily represent the views of those we consulted.

Parts of this health technology assessment are based on data and information compiled and provided by the Canadian Institute for Health Information (CIHI). However, the analyses, conclusions, opinions, and statements expressed in this assessment are those of Ontario Health and not necessarily those of CIHI.

Citation

Ontario Health. Pelvic floor muscle training for stress urinary incontinence, fecal incontinence, and pelvic organ prolapse: a health technology assessment. *Ont Health Technol Assess Ser* [Internet]. 2024 Aug;24(6):1–172. Available from: hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/pelvic-floor-muscle-training-for-stress-urinary-incontinence-fecal-incontinence-and-pelvic-organ-prolapse

A Note About Terminology

As a government agency, Ontario Health can play an active role in ensuring that people of all identities and expressions recognize themselves in what they read and hear from us. We recognize that gender identities are individual and that some people who give birth are not women, despite being assigned female sex at birth. Thus, in this health technology assessment, we use gender-inclusive pronouns and terms as much as possible.

Given the nature of this health technology assessment's topic, which sometimes requires differentiation of conditions, associated treatments and, therefore, also clinical population on the basis of anatomy, we must occasionally use sex organ-based binary definitions – woman, to refer to a person with a vagina, and man, to refer to a person with a penis – and when citing published literature that uses such terms (e.g., “woman,” “women,” “female,” “man,” “men,” “male”), we also use these terms for consistency with these cited studies (where necessary, we may include the study's definition for clarity). In doing so, we only seek to define anatomy and make no assumptions about gender identity or the relationship between a person's sex organs and their gender identity.

Abstract

Background

Stress urinary incontinence, fecal incontinence, and pelvic organ prolapse are common forms of pelvic floor dysfunction. Pelvic floor muscle training is used to improve pelvic floor function, through a program of exercises. We conducted a health technology assessment of pelvic floor muscle training for people with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse, which included an evaluation of effectiveness, safety, and the budget impact of publicly funding pelvic floor muscle training, and patient preferences and values.

Methods

We performed a systematic literature search of the clinical evidence. We assessed the risk of bias of included studies using the ROBIS tool, for systematic reviews, and the Cochrane Risk of Bias tool, for randomized controlled trials, and we assessed the quality of the body of evidence according to Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. We performed a systematic economic literature search but did not conduct a primary economic evaluation. We also analyzed the budget impact of publicly funding pelvic floor muscle training in adults with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse in Ontario. To contextualize the potential value of pelvic floor muscle training as a treatment, we spoke with people with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse.

Results

We included 6 studies (4 systematic reviews and 2 randomized controlled trials) in the clinical evidence review. In comparison with no treatment, pelvic floor muscle training significantly improved symptom severity and increased patient satisfaction in women with stress urinary incontinence or pelvic organ prolapse (GRADE: Moderate). For men with stress urinary incontinence after prostatectomy, pelvic floor muscle training yielded mixed results for symptom improvement (GRADE: Very low). For adults with fecal incontinence, pelvic floor muscle training did not improve symptoms in comparison with standard care (GRADE: Very low).

In the economic literature review, we included 6 cost–utility analyses that had evaluated the cost-effectiveness of pelvic floor muscle training as a treatment for people with pelvic organ prolapse or urinary incontinence. We did not identify any economic studies on pelvic floor muscle training for women or men with fecal incontinence or men with pelvic organ prolapse. The analyses included in our review found that, for women with stress urinary incontinence, pelvic floor muscle training was likely cost-effective in comparison with other nonsurgical interventions. For men with urinary incontinence after prostate surgery, pelvic floor muscle training was likely not cost-effective in comparison with standard care. For women with pelvic organ prolapse, the cost-effectiveness of pelvic floor muscle training in comparison with no active treatment was uncertain.

The average cost of pelvic floor muscle training was approximately \$763 per patient. Publicly funding pelvic floor muscle training for women with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse would result in additional costs over 5 years of \$185.3 million, \$275.6 million, and \$85.8 million, respectively. Publicly funding pelvic floor muscle training for men with stress urinary

incontinence and fecal incontinence would result in additional costs over 5 years of \$10.8 million and \$131.1 million, respectively. The people we spoke with reported that stress urinary incontinence, fecal incontinence, and pelvic organ prolapse limited their social and physical activities, taking a huge emotional toll. Many were hesitant or even fearful of surgery, and most people with experience of pelvic floor muscle training reported that it relieved most or all of their symptoms and allowed them to return to normal daily activities.

Conclusions

Pelvic floor muscle training is likely more effective (with respect to symptom improvement and patient satisfaction) than no treatment for women with stress urinary incontinence or pelvic organ prolapse. Pelvic floor muscle training may yield mixed results with respect to symptom improvement for men with stress urinary incontinence after prostatectomy and have little to no effect on symptom improvement for adults with fecal incontinence. We estimate that publicly funding pelvic floor muscle training for adults with pelvic floor dysfunction (stress urinary incontinence, fecal incontinence, and pelvic organ prolapse) in Ontario would result in a substantial budget increase over the next 5 years. People with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse shared the negative impact these conditions have on their social and physical life and valued pelvic floor muscle training as a nonsurgical treatment option.

Table of Contents

Key Messages	2
Acknowledgements	3
A Note About Terminology	4
Abstract	5
List of Tables	12
List of Figures	14
Objective	15
Background	15
Health Condition	15
<i>Stress Urinary Incontinence</i>	15
<i>Fecal Incontinence</i>	15
<i>Pelvic Organ Prolapse</i>	15
<i>Consequences</i>	16
Clinical Need and Population of Interest	16
<i>Stress Urinary Incontinence</i>	16
<i>Fecal Incontinence</i>	16
<i>Pelvic Floor Dysfunction Risk Factors</i>	17
<i>Pelvic Organ Prolapse</i>	17
Current Treatment Options	17
<i>First-Line Treatments</i>	17
<i>Second-Line Treatments</i>	18
Treatment Under Review	18
Ontario, Canadian, and International Context	19
<i>Ontario</i>	19
<i>Canada</i>	19
<i>International</i>	20
Equity Context	20
Expert Consultation	21
PROSPERO Registration	21
Clinical Evidence	22
Research Question	22

Methods.....	22
<i>Scoping</i>	22
<i>Clinical Literature Search</i>	22
<i>Eligibility Criteria</i>	23
<i>Literature Screening</i>	24
<i>Data Extraction</i>	24
<i>Equity Considerations</i>	25
<i>Analysis</i>	25
<i>Critical Appraisal of Evidence</i>	25
Results	25
<i>Clinical Literature</i>	25
<i>Characteristics of Included Studies</i>	26
<i>Risk of Bias in the Included Studies</i>	28
<i>Stress Urinary Incontinence</i>	28
<i>Fecal Incontinence</i>	41
<i>Pelvic Organ Prolapse</i>	42
<i>Ongoing Studies</i>	49
Discussion	49
<i>Stress Urinary Incontinence</i>	49
<i>Fecal Incontinence</i>	50
<i>Pelvic Organ Prolapse</i>	50
<i>Comment Regarding Blinding in Trials of PFMT</i>	50
Strengths and Limitations.....	51
Conclusions.....	51
<i>Stress Urinary Incontinence</i>	51
<i>Fecal Incontinence</i>	52
<i>Pelvic Organ Prolapse</i>	53
Economic Evidence	54
Research Question.....	54
Methods.....	54
<i>Economic Literature Search</i>	54
<i>Eligibility Criteria</i>	54
<i>Literature Screening</i>	56

<i>Data Extraction</i>	56
<i>Study Applicability and Limitations</i>	56
Results	56
<i>Economic Literature Search</i>	56
<i>Overview of Included Economic Studies</i>	58
<i>Applicability and Limitations of the Included Studies</i>	65
Discussion	65
Conclusions.....	66
Primary Economic Evaluation	67
<i>Stress Urinary Incontinence</i>	67
<i>Fecal Incontinence</i>	67
<i>Pelvic Organ Prolapse</i>	68
Budget Impact Analysis	69
Research Question.....	69
Methods.....	69
<i>Analytic Framework</i>	69
<i>Key Assumptions</i>	69
<i>Population of Interest</i>	69
<i>Current Intervention Mix</i>	72
<i>Uptake of the New Intervention</i>	73
<i>Resources and Costs</i>	75
<i>Internal Validation</i>	77
<i>Analysis</i>	77
Results	81
<i>Reference Case</i>	81
<i>Sensitivity Analysis</i>	82
Discussion	85
<i>Equity Considerations</i>	85
Strengths and Limitations.....	86
Conclusions.....	86
Preferences and Values Evidence	87
Objective.....	87
Background.....	87

Quantitative Evidence	87
<i>Research Questions</i>	87
<i>Methods</i>	88
<i>Results</i>	90
<i>Discussion</i>	93
<i>Conclusions</i>	93
Qualitative Evidence	93
Direct Patient Engagement.....	94
<i>Methods</i>	94
<i>Results</i>	95
<i>Discussion</i>	103
<i>Conclusion</i>	103
Preferences and Values Evidence Discussion	103
<i>Equity Considerations</i>	104
Preferences and Values Evidence Conclusions.....	104
Conclusions of the Health Technology Assessment.....	105
<i>Stress Urinary Incontinence</i>	105
<i>Fecal Incontinence</i>	106
<i>Pelvic Organ Prolapse</i>	106
<i>Pelvic Floor Dysfunction</i>	106
Abbreviations	107
Glossary.....	108
Appendices.....	113
Appendix 1: Literature Search Strategies	113
<i>Clinical Evidence Search</i>	113
<i>Economic Evidence Search</i>	123
<i>Quantitative Evidence of Preferences and Values Search</i>	132
<i>Grey Literature Search</i>	137
<i>Search for Intervention-Related Health State Utilities</i>	138
Appendix 2: Selected Excluded Studies	141
<i>Clinical Evidence</i>	141
<i>Economic Evidence</i>	142
Appendix 3: Characteristics of Included Studies	143

Appendix 4: Critical Appraisal of Clinical Evidence.....	148
Appendix 5: Results of Applicability Checklists for Studies Included in the Economic Literature Review	156
Appendix 6: Additional Data in Budget Impact Analysis	157
Appendix 7: Letter of Information.....	161
Appendix 8: Interview Guide	162
References.....	163

List of Tables

Table 1: First-Line Treatments for Stress Urinary Incontinence, Fecal Incontinence, and Pelvic Organ Prolapse 18

Table 2: Characteristics of Included Systematic Reviews and Randomized Controlled Trials, by Condition 27

Table 3: Summary Results for PFMT Versus No Treatment (or Inactive Control) – Improvement of Symptoms (Women, Stress Urinary Incontinence)..... 28

Table 4: Summary Results for Pessary Versus PFMT – Improvement of Symptoms (Women, Stress Urinary Incontinence) 29

Table 5: Summary Results for PFMT Versus Electrical Stimulation – Improvement of Symptoms (Women, Stress Urinary Incontinence)..... 30

Table 6: Summary Results for PFMT Versus Magnetic Stimulation – Improvement of Symptoms (Women, Stress Urinary Incontinence)..... 31

Table 7: Summary Results for PFMT Versus Vaginal Cones – Improvement of Symptoms (Women, Stress Urinary Incontinence) 32

Table 8: Summary Results for PFMT Versus No Treatment (or Inactive Controls) – Quality of Life (Women, Stress Urinary Incontinence)..... 33

Table 9: Summary Results for PFMT Versus Usual Care – Quality of Life (Women, Urinary Incontinence) 34

Table 10: Summary Results for PFMT Versus Electrical Stimulation – Quality of Life (Women, Stress Urinary Incontinence) 35

Table 11: Summary Results for PFMT Versus Vaginal Cones – Quality of Life (Women, Stress Urinary Incontinence) 36

Table 12: Summary Results for PFMT Versus No Treatment (or Inactive Control) – Satisfaction (Women, Stress Urinary Incontinence)..... 37

Table 13: Summary Results for Pessary Versus PFMT – Satisfaction (Women, Stress Urinary Incontinence) 37

Table 14: Summary Results for PFMT Versus No Treatment – Improvement of Symptoms (Men, Stress Urinary Incontinence) 39

Table 15: Summary Results for PFMT With Biofeedback Versus No Treatment – Improvement of Symptoms (Men, Stress Urinary Incontinence) 40

Table 16: Summary Results for PFMT Versus No Treatment – Quality of Life (Men, Stress Urinary Incontinence) 41

Table 17: Summary Results for PFMT Plus Biofeedback Versus Standard Care – Improvement of Symptoms (Adults, Fecal Incontinence)..... 42

Table 18: Summary Results for PFMT Versus No Treatment (or Inactive Control) – Improvement of Symptoms (Women, Pelvic Organ Prolapse) 44

Table 19: Summary Results for Pessary Versus PFMT – Improvement of Symptoms (Women, Pelvic Organ Prolapse) 46

Table 20: Summary Results for PFMT Versus No Treatment – Quality of Life (Women, Pelvic Organ Prolapse) 47

Table 21: Summary Results for Pessary Versus PFMT – Quality of Life (Women, Pelvic Organ Prolapse). 47

Table 22: Summary Results for PFMT Versus No Treatment – Satisfaction (Women, Pelvic Organ Prolapse) 48

Table 23: Summary Results for Pessary Versus PFMT – Complications (Women, Pelvic Organ Prolapse) 49

Table 24: Results of Economic Literature Review – Summary.....	61
Table 25: Types of Urinary Incontinence	71
Table 26: Projected Estimates for Adults in Ontario With Pelvic Floor Dysfunction	72
Table 27: PFMT Uptake Rates in New Scenario, by Condition and Sex	74
Table 28: Patient Volume Estimates for PFMT in New Scenario, by Condition and Sex	75
Table 29: Parameter Changes for Scenario Analyses.....	80
Table 30: Budget Impact Analysis Results (Reference Case), by Condition and Sex	82
Table 31: Budget Impact Analysis Results (Scenario Analyses)	83
Table 32: Budget Impact Analysis Results (Sensitivity Analyses).....	84
Table 33: Characteristics of Included Studies for Quantitative Evidence	92
Table A1: Characteristics of Included Studies.....	143
Table A2: Risk of Bias ^a Among Systematic Reviews (ROBIS Tool).....	148
Table A3: Risk of Bias ^a Among Randomized Controlled Trials (Cochrane Risk-of-Bias Tool).....	149
Table A4: GRADE Evidence Profile – Comparison of PFMT and No Treatment (Women, Stress Urinary Incontinence)	149
Table A5: GRADE Evidence Profile – Comparison of PFMT and Pessary (Women, Stress Urinary Incontinence)	149
Table A6: GRADE Evidence Profile – Comparison of PFMT and Electrical Stimulation (Women, Stress Urinary Incontinence)	150
Table A7: GRADE Evidence Profile – Comparison of PFMT Plus Electrical Stimulation and Electrical Stimulation Alone (Women, Stress Urinary Incontinence).....	150
Table A8: GRADE Evidence Profile – Comparison of PFMT and Magnetic Stimulation (Women, Stress Urinary Incontinence)	151
Table A9: GRADE Evidence Profile – Comparison of PFMT and Vaginal Cones (Women, Stress Urinary Incontinence)	151
Table A10: GRADE Evidence Profile – Comparison of PFMT and Usual Care (Women, Urinary Incontinence)	152
Table A11: GRADE Evidence Profile – Comparison of PFMT Plus Biofeedback and Electrical Stimulation (Women, Stress Urinary Incontinence).....	152
Table A12: GRADE Evidence Profile – Comparison of Vaginal Cones and PFMT Plus Biofeedback (Women, Stress Urinary Incontinence).....	152
Table A13: GRADE Evidence Profile – Comparison of PFMT and No Treatment, Sham, or Verbal/Written Instructions (Men, Postprostatectomy Stress Urinary Incontinence)	153
Table A14: GRADE Evidence Profile – Comparison of PFMT Plus Biofeedback and No Treatment, Sham, or Verbal/Written Instructions (Men, Postprostatectomy Stress Urinary Incontinence) as Reported ³⁴	154
Table A15: GRADE Evidence Profile – Comparison of PFMT and Standard Care (Men or Nonpregnant Women, Fecal Incontinence)	154
Table A16: GRADE Evidence Profile – Comparison of PFMT and No Treatment or Inactive Control (Women, Pelvic Organ Prolapse)	155
Table A17: GRADE Evidence Profile – Comparison of Pessary and PFMT (Women, Pelvic Organ Prolapse)	155
Table A18: Assessment of the Applicability of Studies Evaluating the Cost-Effectiveness of Pelvic Floor Muscle Training.....	156
Table A19: US Prevalence Data for Symptomatic Pelvic Floor Disorders, Women	157
Table A20: US Prevalence Data for Symptomatic Pelvic Floor Disorders, Men.....	157
Table A21: Ontario Adult Population by Sex, 2018 to 2022	158

Table A22: Estimates of the Number of Adult Women With Common Pelvic Floor Disorders in Ontario in 2022	158
Table A23: Estimates of the Number of Adult Men With Common Pelvic Floor Disorders in Ontario in 2022	159
Table A24: Regrouped Estimates of the Number of People With Common Pelvic Floor Disorders Based on Ontario Population in 2022.....	160

List of Figures

Figure 1: PRISMA Flow Diagram—Clinical Systematic Review	26
Figure 2: PRISMA Flow Diagram – Economic Systematic Review	57
Figure 3: Schematic Model of Budget Impact.....	69
Figure 4: PRISMA Flow Diagram – Quantitative Evidence of Preferences and Values Systematic Review	91

Objective

This health technology assessment evaluates the effectiveness and safety of pelvic floor muscle training for the treatment of people with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse. It also evaluates the cost-effectiveness of pelvic floor muscle training and budget impact of publicly funding pelvic floor muscle training and the experiences, preferences, and values of people with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse.

Background

Health Condition

The pelvic floor is a funnel-shaped structure of connective soft tissue – muscles, tendons, and nerves – that performs functions related to digestion, urination, and reproduction.¹ The term *pelvic floor dysfunction* covers a variety of symptoms and definitions vary; an International Urogynecology Association and International Continence Society consensus report² has 250 separate definitions of associated conditions, signs, and symptoms.¹ The 3 most common and definable conditions are urinary incontinence, fecal incontinence, and pelvic organ prolapse.¹

Stress Urinary Incontinence

Stress urinary incontinence is the involuntary loss of urine upon physical exertion or with an increase in intra-abdominal pressure, such as upon sneezing or coughing.³ Stress urinary incontinence represents 50% of cases of urinary incontinence worldwide and is more prevalent than other types of urinary incontinence in women under 55 years of age.⁴ Risk factors for stress urinary incontinence in women include obesity, menopause, constipation, use of medications that relax the urethral sphincter, the presence of lung disease that causes chronic cough, prior pelvic surgeries, parity (number of pregnancies), giving birth to larger babies, episiotomy, and instrumental vaginal deliveries (e.g., use of forceps).^{3,5} For men, stress urinary incontinence most commonly occurs after prostate surgery (e.g., transurethral resection of the prostate for an enlarged gland or radical prostatectomy for cancer) or radiation treatment.⁴

Fecal Incontinence

Fecal incontinence is the inability to control bowel movements, which results in stool (feces) leaking unexpectedly from the rectum.⁶ With fecal incontinence, also called *bowel incontinence*, people may experience anything ranging from an occasional leakage of stool while passing gas to a complete loss of bowel control. Nearly 70% of community-dwelling women with fecal incontinence report that symptoms began after the age of 40 years.⁷ Risk factors for fecal incontinence include older age, diabetes, urinary incontinence, frequent and loose stools, urinary incontinence, instrumental vaginal delivery, giving birth to a baby weighing more than 4 kg, and multiple chronic illnesses.^{5,7,8}

Pelvic Organ Prolapse

One form of pelvic organ prolapse is the downward descent of the female pelvic organs into or through the vagina.⁹ Prolapse of the anterior vaginal wall (called *cystocele*), which is characterized by downward

movement of the bladder into the anterior vaginal wall, is the most common form of pelvic organ prolapse, detected twice as often as posterior vaginal prolapse (called *rectocele*), characterized by downward movement of the rectum into the posterior vaginal wall) and 3 times more than apical prolapse (uterine or posthysterectomy vaginal vault prolapse).⁹ Vaginal childbirth (particularly when instruments were used to assist in delivery or the baby is born facing the mother's front), multiple pregnancies, advancing age, higher body mass index, straining due to constipation, and prior hysterectomy are the most consistent risk factors for pelvic organ prolapse.^{1,9-11} Pelvic organ prolapse is often associated with stress urinary incontinence; approximately 55% of women with stage 2 pelvic organ prolapse (prolapse to within 1 cm [either side] of the hymen) have concurrent stress urinary incontinence.¹²

With rectal prolapse, the rectum descends through the anus. Rectal prolapse can be defined as *complete*, when the entire wall of the rectum extrudes through the anus, or *partial*, when only the lining of the rectum extrudes through the anus.¹³

Consequences

All of the above conditions may have a negative impact on a person's quality of life, such as loss of independence, embarrassment, fear of leaving home, reduced ability to conduct activities of daily living, and social stigma.^{8,14} In addition, untreated urinary or fecal incontinence may lead to skin infections, rashes, sores, or recurrent urinary tract infections.¹⁵ Untreated pelvic organ prolapse may lead to difficulty emptying bowels or bladder as well as pain and discomfort.^{12,16}

Clinical Need and Population of Interest

Stress Urinary Incontinence

About 50% of women with urinary incontinence report stress urinary incontinence as the primary or sole type of incontinence¹⁷; however, prevalence estimates vary due to the use of different methods by studies with different populations and data are insufficient to be accurate. The prevalence of stress urinary incontinence in women appears to increase with age initially, peak around the fourth or fifth decade, and then decrease with increasing age.¹⁷

The prevalence of postprostatectomy urinary incontinence ranges from 1% to 87%, depending on the definition, timing of evaluation, surgical approach, and who carries out the assessment.¹⁸ Most patients experience transient incontinence immediately after a radical prostatectomy, with complete continence returning within 2 to 3 months.¹⁸ Several studies¹⁹⁻²² report a progressive return of continence up to 1 year after radical prostatectomy, with rates that range from 68% to 97% at 12 months, and further improvement progressing up to 2 years.¹⁸ The most common contributing factor to postprostatectomy urinary incontinence is intrinsic sphincter deficiency, with an incidence that ranges from 67% to 92.4%.¹⁸

Fecal Incontinence

The prevalence of fecal incontinence has been reported as 2% to 24% of the adult population, with 1% to 2% of the adult population experiencing significant impact on daily activities.¹⁴ The estimated prevalence of fecal incontinence in community-dwelling adults in the United States is 8.3%, and fecal incontinence occurs at least weekly in 2.7% of individuals.^{8,23} The prevalence is similar in women (8.9%)

and men (7.7%) and increases with age, from approximately 2.6% in people aged 20 to 29 years up to 16.2% in people aged 70 years and older.^{8,23}

Pelvic Floor Dysfunction Risk Factors

Men and women are exposed to different risk factors for pelvic floor dysfunction (e.g., childbirth-related pelvic floor injury vs. prostate cancer treatment) and, therefore, may experience different rates of urinary incontinence, fecal incontinence, or dual urinary and fecal incontinence.²⁴ With aging, medical conditions that are related to physiological decompensation, such as diabetes, stroke, and cognitive and mobility impairment, appear to influence the occurrence of incontinence more strongly than direct pelvic floor injury.²⁴ This is most evident in the observation that older men and women experience similar rates of fecal incontinence despite the unique potential in women for anal sphincter trauma with vaginal delivery.²⁴ Estimates of the prevalence of dual urinary and fecal incontinence in community-dwelling adults range from 2.5% to 14.5%.²⁴

Pelvic Organ Prolapse

In women, the true prevalence of pelvic organ prolapse is difficult to determine because the condition is typically asymptomatic until the displaced organ descends to or beyond the hymenal ring.²⁵ The findings of a recent review show that, in questionnaire-based population studies with nonpregnant adult women, the prevalence of symptomatic pelvic organ prolapse ranged from 2.9% to 12.1%; however, when basing prolapse on examination findings, the prevalence was 75% to 76%, with a prevalence of 37% to 38% for stage 2 prolapse or higher.²⁵ Among parous women (women who have borne children) the prevalence is estimated to be approximately 50%.^{12,26} For nulliparous women (women who have never borne children) aged 20 to 39 years old, the prevalence is estimated to be 1.6%.²⁷

In the United States, loss of vaginal or uterine support is seen in 30% to 76% of women who present for routine gynecology care; in 3% to 6% of those with loss of support, pelvic structures have descended beyond the vaginal opening.⁹ A population-based study in the United States found that approximately 3% of 1,961 adult women surveyed reported symptomatic vaginal bulging.²⁸

Rectal prolapse is relatively uncommon. In a study conducted in Finland, Kairaluoma et al²⁹ found that approximately 2.5 out of every 100,000 people are diagnosed with complete rectal prolapse each year, and in adults, rectal prolapse is more common in those older than 50 years of age. Rectal prolapse is rare in men – approximately 80% to 90% of adults with rectal prolapse are women.²⁹

Current Treatment Options

First-Line Treatments

Conservative (nonmedication and nonsurgical) treatments for pelvic organ prolapse or stress urinary incontinence include lifestyle and behavioural interventions (e.g., scheduled toileting, reduced caffeine intake), pelvic floor muscle training (supervised by a trained professional such as a nurse practitioner, nurse continence advisor, physician, physiotherapist), and vaginal pessaries.^{1,30} For fecal incontinence, conservative treatments include dietary modifications and pelvic floor muscle training.¹⁴

Table 1: First-Line Treatments for Stress Urinary Incontinence, Fecal Incontinence, and Pelvic Organ Prolapse

Condition	Treatment options		
	Lifestyle and behavioural	Intervention	Device or medication
Stress urinary incontinence			
Women ^{31,32}	Moderating caffeine and fluid intake, losing weight, scheduled voiding	PFMT	Vaginal pessary
Men (after prostatectomy) ^{33,34}	Moderating caffeine intake, modifying diet or fluid intake, losing weight, smoking cessation	PFMT	None specified
Fecal incontinence³⁵			
	Dietary adjustments, absorbent products	PFMT	Stool-bulking or antidiarrheal
Pelvic organ prolapse			
Women ³²	Dietary adjustments to avoid constipation	PFMT	Vaginal pessary
Men ³⁶	Dietary adjustments to avoid constipation	—	—

Abbreviations: PFMT, pelvic floor muscle training.

Second-Line Treatments

Second-line treatments for pelvic organ prolapse or stress urinary incontinence involve surgical intervention (e.g., midurethral sling or pelvic reconstruction).^{1,30} For fecal incontinence, invasive approaches include perianal injectable bulking agents, sacral nerve stimulation, or surgery.^{1,14}

Treatment Under Review

Pelvic floor muscle training is defined as “a structured and individualized program of exercises that aims to improve pelvic floor muscle strength, endurance, power, relaxation, or a combination of these parameters.”³¹

Pelvic floor muscle training can be performed alone or combined with adjunct treatments such as electrical muscle stimulation, biofeedback (a method to enhance a patient’s awareness of correct muscle contraction through visual, auditory, or tactile means), or vaginal cones. These treatments, however, are not recommended by Canadian guidelines – as adjuncts or as treatments on their own – for women with urinary incontinence due to limited evidence.³¹

Pelvic floor muscle training is typically performed under the guidance of a pelvic health physiotherapist.³¹ Although pelvic floor muscle training is commonly classified as physical therapy, it includes both physical and behavioural therapy.³⁷

After specialized training, physiotherapists, physicians, registered nurses, and midwives can provide pelvic floor muscle training. Training typically spans 15 hours (e.g., over a weekend) for physiotherapists, as well as physicians, nurse practitioners, and midwives (Sinéad Dufour, written communication, November 2023).

Ontario, Canadian, and International Context

Ontario

In general, pelvic floor muscle training is not publicly funded, and patients with pelvic floor dysfunction normally pay out of pocket or use private insurance. Physiotherapy coverage amounts vary, depending on an individual's plan, and some private health insurance companies only cover the cost of pelvic floor muscle training if an individual has a referral from a physician.³⁸

Some patients who fulfill certain criteria may be eligible for physiotherapy at a government-funded community physiotherapy clinic if they have a referral from a physician or nurse practitioner.^{38,39} Typically, such a referral is provided to help a patient recover from a recent illness, injury, or surgery.

Currently in Ontario, a limited number of health care professionals (physiotherapists, physicians, registered nurses, and midwives) are trained to provide pelvic floor muscle training, for both women and men (Sinéad Dufour, email communication, November 2023).

Canada

Other Canadian provinces are similar to Ontario regarding the funding status of pelvic floor muscle training.⁴⁰

Institut national d'excellence en santé et en services sociaux

In October 2022, the *Institut national d'excellence en santé et en services sociaux* (INESSS) in Quebec recommended pelvic floor muscle training for the treatment of urinary incontinence in women (postpartum and any other time throughout adulthood).⁴¹ INESSS further recommended that⁴¹:

- Access to pelvic floor muscle training be for a maximum of 10 sessions
- Pelvic floor muscle training be supervised by a qualified physiotherapist with the required expertise
- Pelvic floor muscle training be extended over a period of 12 or more weeks, depending on the patient's specific needs, before reassessing the treatment plan
- Access to pelvic floor muscle training be available more than once, at different times in a woman's life (e.g., perinatal and perimenopausal periods)

Similarly, in May 2023, INESSS recommended pelvic floor muscle training for the treatment of pelvic organ prolapse in women⁴²:

- With access to pelvic floor muscle training for a maximum of 10 sessions
- That pelvic floor muscle training be supervised by a qualified physiotherapist with the necessary expertise
- That pelvic floor muscle training be extended over a period of 16 or more weeks, depending on the patient's needs, before reassessing the treatment plan
- That access to pelvic floor muscle training be available more than once, at different times in a woman's life

INESSS did not recommend pelvic floor muscle training for the treatment of anal dysfunction (including fecal incontinence) due to a low level of evidence.⁴²

Society of Obstetricians and Gynecologists of Canada

In April 2020, the Society of Obstetricians and Gynecologists of Canada recommended pelvic floor muscle training for urinary incontinence and noted that pelvic floor muscle training should not be implemented without appropriate evaluation and adequate patient training and, furthermore, providing the patient with verbal instructions and written handouts alone does not constitute evidence-based pelvic floor muscle training.³¹

International

National Institute of Health and Care Excellence

In the United Kingdom, the National Institute of Health and Care Excellence (NICE) issued the following guidance in December 2021¹:

- For pelvic organ prolapse: Supervised pelvic floor muscle training for at least 4 months for women with symptomatic pelvic organ prolapse that does not extend greater than 1 cm beyond the hymen upon straining
- For stress urinary incontinence: Supervised pelvic floor muscle training for at least 3 months for women (including pregnant women)
- For fecal incontinence with coexisting pelvic organ prolapse: Supervised pelvic floor muscle training for at least 4 months

International Continence Society

In 2023, the International Continence Society recommended pelvic floor muscle training as a conservative treatment option for urinary or fecal incontinence in men and women.⁴³ In addition, the International Continence Society published a consensus report, which stated that pelvic floor muscle training can be offered to women with symptomatic prolapse because it is associated with a reduction in prolapse symptoms and pelvic floor symptoms; however, the report also stated that whether pelvic floor muscle training reduces prolapse stage is uncertain.⁴³

American Urology Association

The American Urology Association recommends that, for patients who have undergone radical prostatectomy, health care professionals should offer pelvic floor muscle exercises or pelvic floor muscle training in the immediate postoperative period.⁴⁴

Equity Context

Some people without a private insurance plan may not be able to afford pelvic floor muscle training, which may cause inequity in health outcomes. Individuals who are poor candidates for surgical intervention and are unable to pay for pelvic floor muscle training may have fewer treatment options from which to choose.

In remote or rural areas, people may have limited access to a provider who is trained to provide pelvic floor muscle training appropriate to a person's needs. Although internet-delivered pelvic floor muscle training is not included in this health technology assessment, the Society of Obstetricians and Gynaecologists of Canada's technical update⁴⁵ recommends the use of eHealth interventions for women with stress urinary incontinence in specific scenarios, for example, if in-person care is not available or accessible.

Expert Consultation

We engaged with experts in the areas of physiotherapy, nursing, and pelvic surgery to help inform our understanding of aspects of the health technology and our methodologies and to contextualize the evidence.

PROSPERO Registration

This health technology assessment has been registered in PROSPERO, the international prospective register of systematic reviews (CRD42023437960), available at crd.york.ac.uk/PROSPERO

Clinical Evidence

Research Question

What are the effectiveness and safety of pelvic floor muscle training compared with no treatment or conservative usual care for the treatment of people with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse?

Methods

Scoping

The scope of the research question encompassed 3 conditions that affect different clinical populations variably; thus, our methodological approach needed to reflect the breadth of the scope.

During scoping of this topic, which included a search of publications from international HTA agencies, we identified a comprehensive systematic review on pelvic floor dysfunction in women conducted by the National Institute for Health and Care Excellence (NICE) in 2021.¹ To be expedient yet comprehensive (in addressing the scope of our research question), we decided to leverage existing information by seeking systematic reviews that, in whole or in part, focused on the clinical populations of interest of this HTA.

In the NICE systematic review¹ that we initially identified, the definition of the comparator suited our purposes, that is, “no treatment or other conservative treatments,”¹ but one type of conservative treatment – treatment with pessary – was excluded. The rationale for that exclusion was not stated; however, NICE published an accompanying systematic review⁴⁶ comparing intravaginal devices for the treatment of pelvic floor dysfunction with pelvic floor muscle training, in which treatments with pessaries were included. Therefore, we also included this systematic review.

The clinical population of interest in these systematic reviews, however, was limited to women.

Therefore, in addition, we identified a 2023 systematic review³⁴ that focused on men with stress urinary incontinence and a 2016 systematic review⁴⁷ that focused on treatments for fecal incontinence for adult men and women. To supplement the base of evidence offered by these systematic reviews, we performed additional literature searches.

Clinical Literature Search

Using the same database search strategies reported in the NICE systematic review,¹ with the exception of date range (NICE search date range: January 1, 1980, to February 2021), we performed a clinical literature search on May 25, 2023, to retrieve studies published since January 1, 2021. We used the Ovid interface in the following databases: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews. We also used the EBSCOhost interface to search the Cumulative Index to Nursing & Allied Health Literature (CINAHL).

The supplemental search was run in the same databases listed above and in the National Health Service Economic Evaluation Database, using filters^{48,49} to capture studies with other genders and expanded concept scopes (e.g., prostatectomy and transgender) published from January 1, 1980, to May 25, 2023.

In addition, we screened the list of studies excluded from the 2021 NICE review to identify any studies that included men. Search strategies were peer-reviewed using the PRESS Checklist.⁵⁰

We created database autoalerts in MEDLINE, Embase, and CINAHL and monitored them until October 4, 2023. We also performed a targeted grey literature search of the International HTA Database, the websites of health technology assessment organizations and regulatory agencies, and clinical trial and systematic review registries, following a standard list of sites developed internally (see Appendix 1 for our literature search strategies, including all search terms).

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text papers
- Systematic reviews of randomized controlled trials. If none, then systematic reviews of other studies (observational)
- Randomized controlled trials

Exclusion Criteria

- Observational studies, editorials, commentaries, case reports, conferences abstracts, letters
- Animal and in vitro studies

Participants

Inclusion Criteria

- People (≥ 12 years) diagnosed with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse

Exclusion Criteria

- People ≤ 11 years of age
- People with pelvic organ prolapse, stress urinary incontinence, or fecal incontinence that is not associated with pelvic floor dysfunction (e.g., if urinary incontinence due to a neurological condition)

Interventions

Inclusion Criteria

- Supervised and guided pelvic floor muscle training for treatment (such as but not limited to Kegel exercises) with or without adjunct (e.g., biofeedback, weighted vaginal cones, and electrical or neuromuscular stimulation) or other conservative treatment (e.g., pessary)

Exclusion Criteria

- Pelvic floor muscle training for prevention
- Unsupervised, unguided pelvic floor muscle training (e.g., pamphlets, DVDs, online)

Comparators

Inclusion Criteria

- No active treatment
- Conservative treatments (i.e., nonsurgical treatments, e.g., pessary)

Exclusion Criteria

- Surgical treatments

Outcomes

- Improvement of symptoms (e.g., general, incontinence, sexual)
- Quality of life
- Prevention of worsening prolapse or incontinence
- Patient satisfaction
- Complications
- Delayed need for surgery; surgeries avoided
- Pelvic floor muscle training adherence

Outcomes are reported for short-term (e.g., ≤ 3 months) and long-term follow-up (e.g., > 3 months), where possible.

Literature Screening

A single reviewer conducted an initial screening of titles and abstracts using Covidence⁵¹ and then obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. A single reviewer then examined the full-text articles and selected studies eligible for inclusion.

Data Extraction

We extracted relevant data on study characteristics and risk-of-bias items as reported by systematic reviews and relevant study data from systematic reviews and randomized controlled trials. We used a data form to collect:

- Source (e.g., citation information, study type)
- Methods (e.g., study design, participant allocation, reporting of outcomes, whether the study compared 2 or more groups)
- Outcomes (e.g., outcomes measured, number of participants for each outcome, time points at which the outcomes were assessed)

Equity Considerations

We used PROGRESS-Plus, a health equity framework recommended by the Campbell and Cochrane Equity Methods Group,⁵² to explore potential inequities for this health technology assessment. Factors that may lead to disadvantage or inequities in the framework include place of residence; race or ethnicity, culture, or language; gender or sex; disability; occupation; religion; education; socioeconomic status; social capital; and other key characteristics that stratify health opportunities and outcomes.

Equity considerations relevant to the effect of pelvic floor muscle training (for patients with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse) across different populations in terms of geographic access or socioeconomic status (e.g., access to private insurance or extended benefits) are reported to the extent that information was available in the included studies.

Analysis

We did not perform quantitative synthesis of the individual studies due to variation in the frequency and type of pelvic floor muscle training offered to patients and heterogeneity in types of outcome measures.⁵³ We were also unable to undertake subgroup analyses (e.g., in terms of geographic access or socioeconomic status) because stratified effect data were not available.

We qualitatively synthesized findings from the systematic reviews with those from the additional studies, by condition (i.e., stress urinary incontinence, fecal incontinence, and pelvic organ prolapse), sex, outcome, and treatment (comparator).

Critical Appraisal of Evidence

We assessed risk of bias using the ROBIS tool⁵⁴ for systematic reviews and the Cochrane Risk of Bias tool⁵⁵ for randomized controlled trials.

We evaluated the quality of the body of evidence for each outcome according to the *Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Handbook*.⁵⁶ The body of evidence was assessed based on the following considerations: risk of bias, inconsistency, indirectness, imprecision, and publication bias. The overall rating reflects our certainty in the evidence.

We report the GRADE and risk of bias assessments as reported by the included systematic reviews. We directly undertook a risk of bias assessment using the Cochrane Risk of Bias tool for randomized controlled trials that we identified but were not reported in the included systematic reviews. When a GRADE assessment was not undertaken by an included systematic review, we undertook the assessment ourselves.

Results

Clinical Literature

The search of the clinical literature yielded 1,792 citations including grey literature searches and after duplicates were removed. We identified 2 additional eligible studies that had been published after the literature search cutoff dates of the included systematic reviews. Figure 1 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for the clinical literature search. See Appendix 2 for a list of selected studies excluded after full-text review.

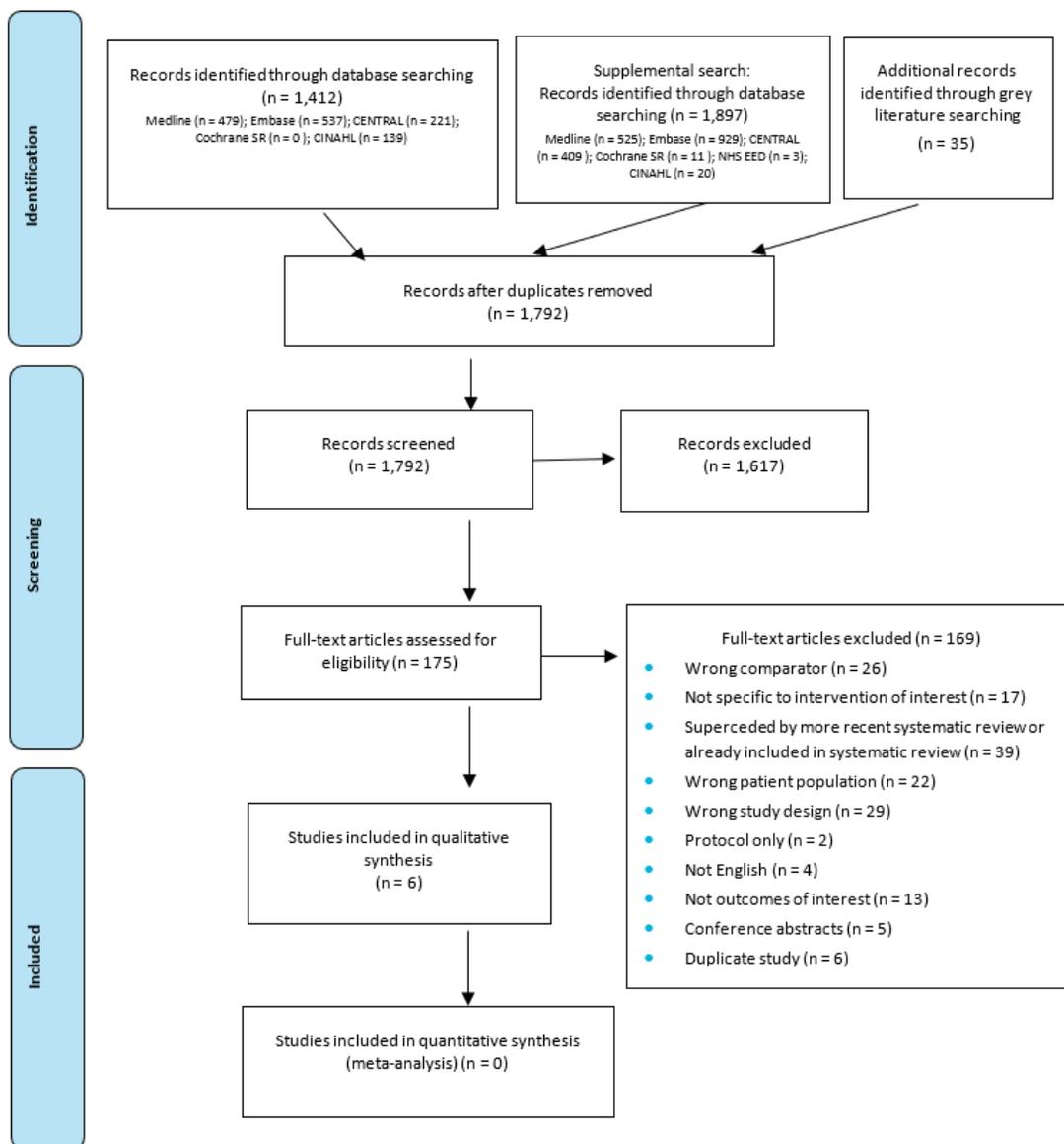


Figure 1: PRISMA Flow Diagram—Clinical Systematic Review

PRISMA flow diagram showing the clinical systematic review. The database search of the clinical literature yielded 3,369 citations. We identified 35 additional eligible studies from other sources. After removing duplicates, we screened the abstracts of 1,792 studies and excluded 1,617. We assessed the full text of 175 articles and excluded a further 169. In the end, we included 6 articles in the qualitative synthesis.

Abbreviation: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.⁵¹

Characteristics of Included Studies

The characteristics of the 4 systematic reviews^{1,34,46,47} and 2 randomized controlled trials^{57,58} that met our inclusion criteria are reported in Table 2. Characteristics of studies that were included in the systematic reviews in Table 2 are shown in Table A1.

Table 2: Characteristics of Included Systematic Reviews and Randomized Controlled Trials, by Condition

Studies	Search range	Population	Intervention	Comparator	Outcomes
Stress urinary incontinence					
Systematic reviews					
NICE, ¹ 2021	Jan 1980–Feb 2021 ^a	Women diagnosed with POP, SUI, or FI	PFMT	No treatment, standard care, or other conservative treatments	Improvement of symptoms, complications, quality of life, adherence, satisfaction
NICE, ⁴⁶ 2021	Jan 1980–Feb 2021 ^a	Women diagnosed with POP, SUI, or FI	Intravaginal devices (including pessary)	PFMT	Improvement of symptoms, complications, quality of life, adherence, satisfaction
Johnson et al, ³⁴ 2023	Jan 1980–Apr 4, 2022	Men diagnosed with SUI postprostatectomy	PFMT	No treatment, standard care, or other conservative treatments	Improvement of symptoms, complications, quality of life, adherence
RCTs					
Sahin et al, ⁵⁷ 2023	NA	Women 18–65 y, with mild or moderate incontinence symptoms	PFMT	Electrical stimulation; PFMT with electrical stimulation	Improvement of symptoms, quality of life
Dudoniene et al, ⁵⁸ 2023	NA	Women 29–49 y, diagnosed with SUI	PFMT	Magnetic stimulation	Improvement of symptoms, complications
Fecal incontinence					
Systematic reviews					
NICE, ¹ 2021	Jan 1980–Feb 2021 ^a	Women diagnosed with POP, SUI, or FI	PFMT	No treatment, standard care, or other conservative treatments	Improvement of symptoms, complications, quality of life, adherence, satisfaction
Forte et al, ⁴⁷ 2016	Jan 1980–Jun 2015	Men and women diagnosed with FI	PFMT	No treatment, standard care, or other conservative treatments	Improvement of symptom, complications, quality of life
RCTs					
None	—	—	—	—	—
Pelvic organ prolapse					
Systematic reviews					
NICE, ¹ 2021	Jan 1980–Feb 2021 ^a	Women diagnosed with POP, SUI, or FI	PFMT	No treatment, standard care, or other conservative treatments	Improvement of symptoms, complications, quality of life, adherence, satisfaction
NICE, ⁴⁶ 2021	Jan 1980–Feb 2021 ^a	Women diagnosed with POP, SUI, or FI	Intravaginal devices (including pessary)	PFMT	Improvement of symptoms, complications, quality of life, adherence, satisfaction
RCTs					
None	—	—	—	—	—

Abbreviations: FI, fecal incontinence; NA, not applicable; PFMT, pelvic floor muscle training; POP, pelvic organ prolapse; RCT, randomized controlled trial; SUI, stress urinary incontinence; y, years.

^aSearches rerun 6 weeks before final submission of the review.

Risk of Bias in the Included Studies

We assessed the risk of bias using the ROBIS tool for all 4 systematic reviews as Low (Appendix 4, Table A2).

We assessed the risk of bias for both randomized controlled trials (Appendix 4, Table A3) as High due to lack of blinding of physiotherapists or participants and incomplete outcome data.

Stress Urinary Incontinence

Women

Improvement of Symptoms

PFMT Versus No Treatment (or Inactive Control)

In general, more people reported improvement in their symptoms with pelvic floor muscle training than those who did not undergo treatment (Table 3); for example, significantly more women reported being cured after 3 to 6 months of pelvic floor muscle training than women who did not undergo treatment (or were inactive control participants).^{1,59} Noting the wide confidence interval in effect estimate (risk ratio [RR] 8.38, 95% confidence interval [CI] 3.68 to 19.07⁵⁹), taking the broad variation of GRADE ratings from different systematic reviews into consideration (which ranged from Very low to High¹), and downgrading for risk of bias (Table A4, Appendix 4), we rated the overall quality of evidence (GRADE) for symptom improvement as Moderate.

Table 3: Summary Results for PFMT Versus No Treatment (or Inactive Control) – Improvement of Symptoms (Women, Stress Urinary Incontinence)

Studies	Measure	PFMT, n/N (%)	No treatment, ^a n/N (%)	Effect estimate		GRADE ^b
				Relative, ratio (95% CI)	Absolute, per 1,000 (95% CI)	
Systematic reviews						
NICE, ¹ 2021						
Dumoulin et al, ⁵⁹ 2018						
4 RCTs	Patient-perceived cure ^c	46/82 (56.1)	5/83 (6.0)	RR 8.38 (3.68 to 19.07)	445 (161 to 1,000)	High
3 RCTs	Patient-perceived cure or improvement ^c	88/119 (73.9)	14/123 (11.4)	RR 6.33 (3.88 to 10.33)	607 (328 to 1,000)	Moderate
Imamura et al, ⁶⁰ 2010						
8 RCTs	Cure rate	70/308 (22.7)	20/297 (6.7)	OR 5.41 (1.64 to 17.82)	214 (39 to 495)	Very low
11 RCTs	Improvement rate	263/361 (72.9)	128/337 (38)	OR 11.75 (3.49 to 39.55)	498 (301 to 581)	Very low
RCTs						
None	—	—	—	—	—	—

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; NICE, National Institute for Health and Care Excellence; OR, odds ratio; RCT, randomized controlled trial; RR, risk ratio.

^aNo treatment or inactive controls.

^bNICE¹ GRADE ratings.

^cTreatment duration: 3–6 months.

PFMT Versus Other Conservative Treatments

Pessary

Richter et al⁶¹ and Kenton et al⁶² compared symptom improvement after treatment with a pessary with that after pelvic floor muscle training and the combination of treatment with both. Overall, people using pessaries were significantly more likely to report bothersome symptoms compared with pelvic floor muscle training alone at the 3-month follow-up. However, at the 12-month follow-up, this difference narrowed, and there was no significant difference between the treatment groups (Table 4). After 3 months, people using pessaries alone were significantly less likely to report that their continence improved compared with people using pessaries in combination with pelvic floor muscle training. However, by 12 months, there was no significant difference between the treatment groups (Table 4).

We rated the overall quality of evidence (GRADE) as Low, downgrading for risk of bias (Table A5, Appendix 4).

Table 4: Summary Results for Pessary Versus PFMT – Improvement of Symptoms (Women, Stress Urinary Incontinence)

Studies	Measure	Pessary (N = 149)	PFMT (N = 146)	Pessary and PFMT (N = 150)		
		n or mean (SD) ^a	n or mean (SD) ^a	RR (95% CI) or mean difference (95% CI) ^a	n RR (95% CI)	
Systematic reviews						
NICE, ⁴⁶ 2021						
2 RCTs ^{61,62}	Better continence ^b					
	3 mo	59	72	0.80 (0.62 to 1.04)	80	0.74 (0.58 to 0.95)
	12 mo	47	48	0.96 (0.69 to 1.34)	49	0.97 (0.69 to 1.34)
	No bothersome symptoms ^c					
	3 mo	49	71	0.68 (0.51 to 0.90)	66	0.75 (0.56 to 1.00)
	12 mo	52	59	0.86 (0.64 to 1.16)	49	1.07 (0.78 to 1.47)
	> 75% reduction weekly incontinence episodes					
	3 mo	69	68	0.99 (0.78 to 1.27)	80	0.87 (0.69 to 1.34)
	12 mo	51	54	0.93 (0.68 to 1.26)	52	0.99 (0.72 to 1.35)
	Change in UIQ score (possible range 0–300), 3 mo	-31.4 (50) ^a	-32.1 (38.4) ^a	0.70 (-9.46 to 10.86) ^a	—	—
	Change in UDI score (possible range 0–300), 3 mo	-33.9 (38.5) ^a	-30.7 (33.4) ^a	-3.20 (-11.42 to 5.02) ^a	—	—
	Change in QUID stress score (possible range 0–15), 3 mo	-4.2 (6.2) ^a	-4.0 (3.6) ^a	-0.20 (-1.35 to 0.95) ^a	—	—
RCTs						
None	—	—	—	—	—	—

Abbreviations: CI, confidence interval; PFMT, pelvic floor muscle training; PFDI, Pelvic Floor Distress Inventory; PGI-I, Patient Global Impression of Improvement; QUID, Questionnaire for Urinary Incontinence Diagnosis; RR, risk ratio; SD, standard deviation; UDI, urinary distress inventory; UIQ, Urinary Impact Questionnaire.

^aDenotes the value is the second of the 2 types listed for the column, i.e., mean (SD) or mean difference (95%CI).

^bImproved PGI-I score.

^cUsing UDI subscale (of PFDI).

Source: Data from Ontario Health.³⁰

Electrical Stimulation

Although most evidence showed no significant difference in symptom improvement between groups treated with pelvic floor muscle training and those treated with electrical stimulation (Table 5); Stewart et al⁶³ found that more women reported being cured with pelvic floor muscle training than did with electrical stimulation treatment (RR 1.75, 95% CI 1.15 to 2.68).

In the additional randomized controlled trial⁵⁷ that was identified in our literature search, after women underwent 8 weeks of treatment with either pelvic floor muscle training or electrical stimulation, there was no significant difference in treatment group proportions of those reporting improvement in symptoms ($P = .83$) or being cured ($P = .83$).

We rated the overall quality of evidence (GRADE) as Very low, downgrading for risk of bias and imprecision (Table A6, Appendix 4).

Table 5: Summary Results for PFMT Versus Electrical Stimulation – Improvement of Symptoms (Women, Stress Urinary Incontinence)

Studies	Measure	PFMT, n/N (%)	Electrical stimulation, n/N (%)	Effect estimate		GRADE ^b
				Relative, ratio (95% CI)	Absolute, per 1,000 (95% CI)	
Systematic reviews						
NICE, ¹ 2021						
Imamura et al, ⁶⁰ 2010						
5 RCTs	Cure rate	15/62 (24.2)	7/62 (11.3)	OR 2.65 (0.82 to 8.60)	139 (-18 to 410)	Very low
6 RCTs	Improvement rate	69/92 (75)	57/98 (58.2)	OR 2.18 (0.76 to 6.28)	170 (-68 to 316)	Very low
Stewart et al, ⁶³ 2017						
4 RCTs	Subjective cure	36/71 (50.7)	21/72 (29.2)	RR 1.75 (1.15 to 2.68)	219 (44 to 490)	Very low
7 RCTs	Subjective cure or improvement rate	79/118 (66.9)	73/126 (57.9)	RR 1.18 (0.97 to 1.43)	104 (-17 to 249)	Very low
RCTs						
Sahin et al, ⁵⁷ 2022						
	Cure	12/17	13/17	NR	NR	NA
	Improvement	4/17	3/17	NR	NR	NA
	Cure	10/17 ^a	13/17	NR	NR	NA
	Improvement	3/17 ^a	6/17	NR	NR	NA

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; NA, not applicable; NR, not reported; OR, odds ratio; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; RR, risk ratio.

^aThe intervention for these values was PFMT in addition to electrical stimulation.

^bNICE¹ GRADE ratings.

For pelvic floor muscle training in combination with electrical stimulation, Sahin et al⁵⁷ reported no significant difference in number of women who reported improvement of their symptoms ($P = .83$; see also Table 5) or cure ($P = .83$) in comparison with electrical stimulation alone.

We rated the overall quality of evidence (GRADE) as Very low, downgrading for risk of bias and imprecision (Table A7, Appendix 4).

Magnetic Stimulation

Dudoniene et al⁵⁸ found no significant difference in change in self-reported symptom severity between women who underwent pelvic floor muscle training compared with those who underwent magnetic stimulation treatment (International Consultation on Incontinence Questionnaire–Short Form score: $P = .51$, Incontinence Impact Questionnaire score: $P = .70$; Table 6).

We rated the overall quality of evidence (GRADE) as Very low, downgrading for risk of bias and imprecision (Table A8, Appendix 4).

Table 6: Summary Results for PFMT Versus Magnetic Stimulation – Improvement of Symptoms (Women, Stress Urinary Incontinence)

Studies	Measure	PFMT, mean difference ^a (SD)	Magnetic stimulation, mean difference ^a (SD)	Comparison between groups, P value
Systematic reviews				
None	—	—	—	—
RCTs				
Dudoniene et al, ⁵⁸ 2023	Symptom severity (ICIQ-SF)	4.67 (2.99)	4.08 (3.08)	.51
	Symptom severity (IIQ-7 score)	22.50 (19.26)	20.58 (14.57)	.70

Abbreviations: ICIQ-SF, International Consultation on Incontinence Questionnaire–Short Form; IIQ-7, Incontinence Impact Questionnaire; PFMT, pelvic floor muscle training; SD, standard deviation.

^aMean difference = pre score – post score.

Vaginal Cones

There was no significant difference in symptom improvement between pelvic floor muscle training and treatment with vaginal cones (Table 7). Taking into account the variation of quality of evidence (GRADE) reported by NICE,¹ which ranged from Very low to Low, and downgrading for risk of bias and imprecision (Table A9, Appendix 4), we rated the overall quality of evidence as Very low.

Table 7: Summary Results for PFMT Versus Vaginal Cones – Improvement of Symptoms (Women, Stress Urinary Incontinence)

Studies	Measure	PFMT, n/N (%)	Vaginal cone, n/N (%)	Effect estimate		GRADE ^a
				Relative, ratio (95% CI)	Absolute, per 1,000 (95% CI)	
Systematic reviews						
NICE, ¹ 2021						
Herbison et al, ⁶⁴ 2013						
6 RCTs	No subjective improvement or cure	73/180 (40.6)	68/178 (38.2)	RR 1.03 (0.8 to 1.33)	11 (-76 to 126)	Very low
5 RCTs	No subjective cure	128/169 (75.7)	129/169 (76.3)	RR 0.99 (0.88 to 1.12)	-8 (-92 to 92)	Low
Imamura et al, ⁶⁰ 2010						
3 RCTs	Cure rate	6/12 (5.0)	11/124 (8.9)	OR 0.61 (0.09 to 3.95)	-33 (-80 to 189)	Very low
5 RCTs	Improvement rate	110/167 (65.9)	108/164 (65.9)	OR 1.01 (0.52 to 1.95)	2 (-158 to 131)	Very low
RCTs						
None	—	—	—	—	—	—

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; OR, odds ratio; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; RR, relative risk.

^aNICE¹ GRADE ratings.

Quality of Life

PFMT Versus No Treatment (or Inactive Control)

Moroni et al⁶⁵ found that incontinence-specific quality of life was significantly better for people who underwent pelvic floor muscle training when compared with no treatment (or inactive controls) (Table 8).

GRADE ratings from systematic reviews on improvement in quality of life ranged from Very low to Moderate. Taking this variation (Table 8) into consideration, noting that a scale specific to incontinence was included in only 1 review,⁶⁵ and downgrading for risk of bias and imprecision, we rated the overall quality of evidence (GRADE) as Very low (Table A4, Appendix 4).

Table 8: Summary Results for PFMT Versus No Treatment (or Inactive Controls) – Quality of Life (Women, Stress Urinary Incontinence)

Studies	Measure	PFMT, n	No treatment, n	Effect estimate		GRADE ^b
				Relative	Absolute, mean difference (95% CI); in favour of ^a	
Systematic reviews						
NICE, ¹ 2021						
Dumoulin et al, ⁵⁹ 2018						
3 RCTs	King's Health Questionnaire general health score	80	65	—	1.81 (-3.40 to 7.03); no treatment	Moderate
Imamura et al, ⁶⁰ 2010						
1 RCT	Social Activity Index	25	30	—	0.80 (0.08 to 1.52); PFMT	Very low
1 RCT	Quality of Life Scale (Norwegian)	25	30	—	4.90 (-0.80 to 10.60); PFMT	Very low
Moroni et al, ⁶⁵ 2016						
2 RCTs	Incontinence-specific quality of life	34	33	—	-1.24 (-1.77 to -0.71); PFMT	Very low
RCTs						
None	—	—	—	—	—	—

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

^a Since positive and negative mean difference values have different meanings for the tools and scores used to assess quality of life, the treatment for which the direction of movement (i.e., the mean difference value) is in favour is included alongside.

^b NICE¹ GRADE ratings.

PFMT Versus Other Conservative Treatments

Usual Care

Women who underwent antenatal pelvic floor muscle training for fecal or urinary incontinence treatment reported better overall quality of life than those who received usual care; however, quality of life was not significantly different for postnatal pelvic floor muscle training compared with usual care (Table 9).

Table 9: Summary Results for PFMT Versus Usual Care – Quality of Life (Women, Urinary Incontinence)

Studies	Measure	PFMT, n	Other, n	Effect estimate		GRADE ^b
				Relative	Absolute, mean difference (95% CI); in favour of ^a	
Systematic reviews						
NICE, ¹ 2021						
Woodley et al, ⁶⁶ 2020						
1 RCT	Urinary incontinence-specific (ICIQ-SF), antenatal	20	21	—	-3.5 (-6.13 to -0.87); PFMT	Very low
1 RCT	Incontinence-specific (BFLUTS), postnatal	9	9	—	-1.66 (-3.51 to 0.19)	Very low
RCTs						
None	—	—	—	—	—	—

Abbreviations: BFLUTS, British Female Lower Urinary Tract Symptoms questionnaire; CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; ICIQ-SF, International Consultation on Incontinence Questionnaire–Short Form; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

^a Since positive and negative mean difference values have different meanings for the tools and scores used to assess quality of life, the treatment that the direction of movement (i.e., the mean difference value) is in favour of is included alongside.

^b NICE¹ GRADE ratings.

NICE rated the quality of the evidence (GRADE) as Very low, downgrading for risk of bias and imprecision (Table A10, Appendix 4).

Electrical Stimulation

Overall, women with stress urinary incontinence who underwent pelvic floor muscle training had significantly better quality of life scores than those who received electrical stimulation (Table 10).

Sahin et al⁵⁷ reported no significant difference in quality of life between women with stress urinary incontinence who received pelvic floor muscle training and those who underwent electrical stimulation. Both type of treatments yielded symptom improvements: There were significant differences between pre- and postintervention scores within groups ($P < .001$ for both). Similarly, Sahin et al⁵⁷ reported no significant difference in quality of life between pelvic floor muscle training in combination with electrical stimulation and electrical stimulation alone for women with stress urinary incontinence. However, there were significant differences between pre- and postintervention scores within groups ($P < .001$ for both).

We rated the overall quality of evidence (GRADE) as Very low, downgrading for risk of bias and imprecision (Table A6, Table A7, and Table A11; Appendix 4).

Table 10: Summary Results for PFMT Versus Electrical Stimulation – Quality of Life (Women, Stress Urinary Incontinence)

Studies	Measure	PFMT, median (IQR)	Electrical stimulation, median (IQR)	Effect estimate		Finding
				Relative	Absolute, mean difference (95% CI)	
Systematic reviews						
NICE, ¹ 2021						
Liang et al, ⁶⁷ 2018						
17 ^a RCTs (2 RCTs for electrical stimulation)	ICIQ-SF (lower better)	—	NR	—	-6.96 (-10.2 to -3.72)	GRADE ^b : Very low
17 ^a RCTs (2 RCTs for electrical stimulation)	ICIQ-SF (lower better)	—	NR	—	-7.12 (-11.08 to -3.16)	GRADE ^b : Very low
RCTs						
Sahin et al, ⁵⁷ 2022	King's Health Questionnaire, posttreatment ^c	2 (1–3.5)	3 (1.5–8.5)	—	—	<i>P</i> = .196
	King's Health Questionnaire, posttreatment ^d	2 (0–4) ^e	3 (1.5–8.5)	—	—	<i>P</i> = .177

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; ICIQ-SF, International Consultation on Incontinence Questionnaire–Short Form; IQR, interquartile range; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

^aNumber of studies in total network meta-analysis.

^bNICE¹ GRADE ratings.

^cPFMT with biofeedback.

^dPFMT in combination with electrical stimulation.

^eIt is specified that the *P* values (in the table) are for the posttreatment comparison. Pretreatment median (IQR) values are also reported – PFMT: 10 (7–13); electrical stimulation: 14 (10.5–16), and PFMT plus electrical stimulation: 12 (7–18.5) – but *P* values for pretreatment comparisons are not reported.

Vaginal Cones

Quality of life did not significantly change for women who underwent pelvic floor muscle training (with or without biofeedback) compared with those who received vaginal cones for the treatment of stress urinary incontinence (Table 11).

Taking variation of quality of evidence (GRADE) ratings (which ranged from Low to Moderate) from different systematic reviews into consideration, noting the wide confidence interval for 1 set of evidence (mean difference -0.56, 95% CI -8.40 to 7.28⁶⁵), and downgrading for risk of bias, we rated the overall quality of evidence as Low (Table A6 and Table A12, Appendix 4).

Table 11: Summary Results for PFMT Versus Vaginal Cones – Quality of Life (Women, Stress Urinary Incontinence)

Studies	Measure	PFMT, n	No treatment, n	Effect estimate		GRADE ^a
				Relative	Absolute, mean difference (95% CI)	
Systematic reviews						
NICE, ¹ 2021						
Imamura et al, ⁶⁰ 2010						
2 RCTs	King's Health Questionnaire, Social Activity Index	41	57	—	0.32 (–0.08 to 0.73) ^b	Low
Moroni et al, ⁶⁵ 2016						
2 RCTs	King's Health Questionnaire, Incontinence-specific Quality of Life	39	39	—	–0.56 (–8.40 to 7.28)	Moderate
Liang et al, ⁶⁷ 2018						
17 ^c RCTs (1 RCT for vaginal cones)	ICIQ-SF	—	—	—	0.01 (–2.62 to 2.64)	Low
17 ^c RCTs (1 RCT for vaginal cones)	ICIQ-SF	—	—	—	0.14 (–3.34 to 3.62)	Low
RCTs						
None		—	—	—	—	—

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; PFMT, pelvic floor muscle training; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; RCT, randomized controlled trial.

^aNICE¹ GRADE ratings.

^bStandardized mean difference.

^cNumber of studies in total network meta-analysis.

Satisfaction

PFMT Versus No Treatment (or Inactive Control)

Significantly more women who underwent pelvic floor muscle training were satisfied with treatment compared with those who had no treatment (Table 12); NICE downgraded for risk of bias and rated the quality of the evidence (GRADE) as Moderate, (Table A4, Appendix 4); we did not identify any additional studies.

Table 12: Summary Results for PFMT Versus No Treatment (or Inactive Control) – Satisfaction (Women, Stress Urinary Incontinence)

Studies	Measure	PFMT, n/N (%)	No treatment, n/N (%)	Effect estimate		GRADE ^a
				RR (95% CI)	Absolute, per 1,000 (95% CI)	
Systematic reviews						
NICE, ¹ 2021						
Dumoulin et al, ⁵⁹ 2018						
2 RCTs	Participant-perceived satisfaction	36/51 (70.6)	7/54 (13.0)	5.32 (2.63 to 10.74)	560 (211 to 1,000)	Moderate
RCTs						
None	—	—	—	—	—	—

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; RR, risk ratio.

^aNICE¹ GRADE ratings.

PFMT Versus Other Conservative Treatments

Pessary

There were no significant differences in satisfaction between treatment with a pessary and treatment with pelvic floor muscle training at either 3- or 12-month follow-ups (Table 13), while fewer people treated with pessaries alone were satisfied with treatment at their 3-month follow-up compared with people who were treated with a pessary and pelvic floor muscle training.⁶¹ By the 12-month follow-up, proportions were similar.⁶¹

Table 13: Summary Results for Pessary Versus PFMT – Satisfaction (Women, Stress Urinary Incontinence)

Studies	Measure	Pessary (N=149)		PFMT (N=146)		Pessary and PFMT (N=150)	
		n		n	RR (95% CI)	n	RR (95% CI)
Systematic reviews							
NICE, ⁴⁶ 2021							
1 RCT ⁶¹	Satisfaction with treatment (PSQ)						
	3 mo	94		110	0.87 (0.75 to 1.02)	118	0.82 (0.71 to 0.95)
	12 mo	75		79	0.97 (0.78 to 1.21)	81	0.95 (0.77 to 1.18)
RCTs							
None	—	—		—	—	—	—

Abbreviations: CI, confidence interval; PFMT, pelvic floor muscle training; PSQ, Patient Satisfaction Questionnaire; RR, risk ratio.

Source: Data from Ontario Health.³⁰

We rated the overall quality of evidence (GRADE) for pessary compared with pelvic floor muscle training, and pessary alone compared with pessary plus pelvic floor muscle training as Low, downgrading for risk of bias (Table A5, Appendix 4).

Complications

We are only aware of 1 study⁵⁸ reporting whether adverse events were experienced; Dudoniene et al⁵⁸ stated that no adverse events were reported by patients who underwent pelvic floor muscle training (n = 24) or magnetic stimulation (n = 24).

We rated the overall quality of evidence as Very low, downgrading for risk of bias and imprecision (Table A8, Appendix 4).

Men

Improvement of Symptoms

PFMT Versus No Treatment

Johnson et al³⁴ reported that it was not possible to pool data from the 2 studies^{68,69} that reported subjectively measured cure or improvement of stress urinary incontinence symptoms between 3 and 6 months after pelvic floor muscle training compared with control; however, descriptive statistics were reported (Table 14).

Between 3 and 6 months, there was a significant improvement in objectively measured findings of stress urinary incontinence in men who underwent pelvic floor muscle training compared with those who were untreated (RR 1.50, 95% CI 1.33 to 1.69); however, between 6 and 12 months, there was no significant difference (RR 1.40, 95% CI 0.80 to 2.44).

Johnson et al³⁴ did not report GRADE ratings for these outcomes. For subjectively measured outcomes, we rated the overall quality of evidence as Very low, downgrading for risk of bias and imprecision (Table A13, Appendix 4). For objectively measured outcomes, we rated the overall quality of evidence as Very low, downgrading for risk of bias and imprecision (Table A13, Appendix 4).

Table 14: Summary Results for PFMT Versus No Treatment – Improvement of Symptoms (Men, Stress Urinary Incontinence)

Studies	Measure	PFMT n/N; median (range)	No treatment ^a n/N; median (range)	Effect estimate	
				Relative, ratio (95% CI)	Absolute, per 1,000
Systematic reviews					
Johnson et al, ³⁴ 2023					
Subjectively measured					
1 RCT ⁶⁸	ICS Male Questionnaire (completely dry or occasional leakage), 6 mo	144/150; — (—)	97/150; — (—)	—	—
1 RCT ⁶⁹	IPSS (urinary symptoms), 0 (mild) to 35 (severe), 6 mo	41/—; 4.0 (0.0–23.0)	40/—; 4.0 (0.0–18.0)	—	—
Objectively measured					
2 RCT ^{68,70}	Improvement, 24-h pad test, 3–6 mo	394	—	RR 1.50 (1.33 to 1.69)	892 for PFMT; 595 for control
2 RCT ^{68,70}	Improvement, 24-h pad test, 6–12 mo	394	—	RR 1.40 (0.80 to 2.44)	1,000 for PFMT; 784 for control
RCTs					
None	—	—	—	—	—

Abbreviations: ICS, International Continence Society; IPSS, International Prostate Symptom Score; PFMT, pelvic floor muscle training; mo, months; RCT, randomized controlled trial; RR, risk ratio.

^aNo treatment encompassed control groups that received no instructions^{68,70} or interventions.⁶⁹

For pelvic floor muscle training with biofeedback compared with control (placebo therapy), 1 study⁷¹ reported subjective cure or improvement of stress urinary incontinence at 6 months and 12 months, 3 studies⁷¹⁻⁷³ reported objectively measured urinary incontinence findings of symptom improvement or cure between 3 and 6 months, and 2 studies reported objectively measured findings between 6 and 12 months. Johnson et al³⁴ did not report comparative statistics for these studies. For subjectively measured outcomes, Johnson et al³⁴ downgraded for risk of bias and imprecision and rated the quality of evidence (GRADE) as Very low. For objectively measured outcomes, Johnson et al³⁴ downgraded for risk of bias and rated the quality of evidence as Low (Table A14, Appendix 4).

Table 15: Summary Results for PFMT With Biofeedback Versus No Treatment – Improvement of Symptoms (Men, Stress Urinary Incontinence)

Studies	Measure	PFMT n/N (%) ^a	No treatment ^a n/N (%) ^b	Effect estimate	
				Relative	Absolute, per 1,000
Systematic reviews					
Johnson et al, ³⁴ 2023					
Subjectively measured					
1 RCT ⁷¹	Cure (visual analog scale), 6 mo	29/50 (57)	27/52 (52)	—	—
	Cure (visual analog scale), 12 mo	26/50 (52)	22/52 (42)	—	—
Objectively measured					
≤ 6 mo					
3 RCTs ⁷¹⁻⁷³	8 g or less on 24-h pad test, 16 wk ⁷²	41/94 (44)	32/80 (40)	—	—
	No leakage for 3 d (consecutive) on 24-h pad test, 6 mo ⁷³	21/60 (35)	32/60 (53)	—	—
	Urine loss, 24-h pad test, 6 mo ⁷¹	Mean 5 g (n = 50) ^a	Mean 3 g (n = 52) ^a	—	—
12 mo					
2 RCTs ^{71,72}	8 g or less on 24-h pad test, 12 mo ⁷²	53/89 (60)	47/78 (64)	—	—
	Urine loss, 24-h pad test, 12 mo ⁷¹	Mean 8 g (n = 50) ^a	Mean 3 g (n = 50) ^a	—	—
RCTs					
None	—	—	—	—	—

Abbreviations: d, days; h, hours; mo, months; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; wk, weeks.

^aNo treatment encompassed control groups that received no intervention,⁷³ placebo therapy,⁷¹ or only written and verbal instructions.⁷²

^bUnless noted otherwise.

Quality of Life

PFMT Versus No Treatment

Johnson et al³⁴ identified 3 studies^{69,74,75} that reported quality of life between 3 and 6 months after pelvic floor muscle training compared with control (no intervention^{69,75} or verbal and written instruction⁷⁴) but with inconsistent findings (i.e., suggesting slight improvement, no difference, and a negative effect on quality of life for men undertaking pelvic floor muscle training; Table 16). Johnson et al³⁴ reported descriptive statistics but did not report comparative statistics.

No studies reported data on quality of life between 6 and 12 months.

Johnson et al³⁴ did not report GRADE ratings for this outcome. We rated the quality of evidence as Very low, downgrading for risk of bias and inconsistency (Table A13, Appendix 4).

Table 16: Summary Results for PFMT Versus No Treatment – Quality of Life (Men, Stress Urinary Incontinence)

Studies	Measure	PFMT n/N; median (IQR or range)	No treatment ^a n/N; median (IQR or range)	Effect estimate	
				Relative, ratio (95% CI)	Absolute, per 1,000
Systematic reviews					
Johnson et al, ³⁴ 2023					
1 RCT ⁶⁹	ICIQ-SF ^b	Median 3.0 (range 0–16.0); n = 41	Median 4.0 (range 0– 21); n = 40	—	—
1 RCT ⁷⁴	Number responding yes to Symptom Inventory question 1 ^c	3/18	3/21	—	—
1 RCT ⁷⁵	EPIC-26 incontinence subscale ^d	Median 6 (IQR 3, range 0–9); n = 19	Median 9 (IQR 1, range 7–10), n = 15	—	—
RCTs					
None	—	—	—	—	—

Abbreviations: EPIC, Expanded Prostate Cancer Index Composite; ICIQ-SF, International Consultation on Incontinence–Short Form; PFMT, pelvic floor muscle training.

^aNo treatment encompassed control groups that received no intervention⁶⁹ or only written and verbal instructions.⁷⁴

^bPossible score range is 0–21, and lower is better.

^cSymptom Inventory Question 1: “Does urine leakage affect your life?”

^dLower score is worse.

Complications

One study⁷⁴ reported that 1 patient complained of rectal pain during pelvic floor muscle training exercises. No adverse events were reported in the control group. No numerical descriptive data were reported by Johnson et al.³⁴ Johnson et al³⁴ downgraded for risk of bias and imprecision and rated the quality of evidence (GRADE) as Very low (Table A13, Appendix 4).

Another⁷² reported no adverse events were experienced by either men who underwent pelvic floor muscle training plus biofeedback or men in the control group. Johnson et al rated the quality of evidence as Very low, downgrading for risk of bias and imprecision (Table A14, Appendix 4).

Fecal Incontinence

Adults

Improvement of Symptoms

Forte et al⁴⁷ identified 2 randomized controlled trials^{76,77} that reported on symptom improvement; we did not identify any additional studies. Overall, there were no significant differences between pelvic floor muscle training with biofeedback when compared with standard care (Table 17).

We rated the overall quality of evidence (GRADE) as Very low, downgrading for risk of bias and imprecision (Table A15, Appendix 4).

Table 17: Summary Results for PFMT Plus Biofeedback Versus Standard Care – Improvement of Symptoms (Adults, Fecal Incontinence)

Systematic review information	Measure	PFMT with biofeedback, mean (SD) ^a	Standard care, mean (SD) ^a	Comparison between groups, P value
Systematic reviews				
Forte et al, ⁴⁷ 2016				
1 RCT ⁷⁷	Self-assessed score of treatment effectiveness ^b	2.3 (1.5)	1.7 (2.0)	.06
	Self-assessed symptom change (very improved, improved, stable, worse)	n (%): 15 (22), 35 (52), 17 (25), 0 (0)	n (%): 13 (17), 34 (45), 23 (31), 5 (7)	.13
	Cleveland Clinic Fecal Incontinence Score	10.1 (3.9)	10.7 (3.8)	.41
	Knowles-Eccersley-Scott-Symptom Questionnaire for Constipation	7.0 (7.5)	10.1 (7.7)	.38
	SF-12 ^c	NR	NR	NR
1 RCT ⁷⁶	Self-assessed score of treatment effectiveness ^b and symptom change (very improved, improved, stable, worse)	NR	NR	.54
	Frequency of bowel actions per day	NR	NR	.71
	Vaizey Fecal Incontinence Score	NR	NR	.54
	Proportion taking antidiarrheal medication	NR	NR	.71
	SF-36, ^d any domain	NR	NR	NR
	Hospital Anxiety and Depression scale score, anxiety	NR	NR	.53
	Hospital Anxiety and Depression scale score, depression	NR	NR	.46
RCTs				
None	—	—	—	—

Abbreviations: PFMT, pelvic floor muscle training; SF-12, Short-Form 12; SF-36, Short-Form 36.

^aUnless noted otherwise.

^bPatient's own view of effectiveness of treatment was rated as "worse," "same," "improved," or "cured," and rated change on ordinal scale of -5 to +5.

^cMedical Outcomes Study 12-item health survey.

^dMedical Outcomes Study 36-item health survey.

Pelvic Organ Prolapse

Women

Improvement of Symptoms

PFMT Versus No Treatment (or Inactive Control)

For this outcome, NICE assessed 2 systematic reviews and 2 randomized controlled trials; we did not identify any additional studies.

In general, patients who underwent pelvic floor muscle training showed significant improvement in their symptoms compared to no treatment (or inactive control).¹ For example, Hagen et al⁷⁸ showed that

statistically significantly fewer women in the pelvic floor muscle training study group self-reported no improvement in their prolapse symptoms (RR 0.48, 95% CI 0.26 to 0.91; Table 18).

Taking this wide variation of GRADE ratings (ranging from Very low to High) into consideration, noting the narrow 95% confidence intervals reported for several effect estimates by Hagen et al,⁷⁸ and downgrading for risk of bias, we rated the overall quality of evidence as Moderate (Table A16, Appendix 4).

Table 18: Summary Results for PFMT Versus No Treatment (or Inactive Control) – Improvement of Symptoms (Women, Pelvic Organ Prolapse)

Studies	Measure	PFMT, n/N (%)	No treatment, n/N (%)	Effect estimate		GRADE ^a
				Relative, ratio (95% CI)	Absolute, per 1,000 (95% CI) unless otherwise indicated	
Systematic reviews						
NICE, ¹ 2021						
1 RCT ⁷⁹	Recurrence of symptoms, 6 mo	13/71 (18.3)	16/73 (21.9)	RR 0.84 (0.43 to 1.61)	-35 (-125 to 134)	Very low
	Sensation of vaginal bulge, VAS 0–100, ^a 6 mo	73	75	—	MD 1.4 (-4.02 to 6.82)	Low
	Improvement in symptoms, 6 mo	62/69 (89.9)	68/72 (94.4)	RR 0.95 (0.86 to 1.05)	-47 (-132 to 47)	Low
1 RCT ⁸⁰	POPDI, ^a 60 d	47	43	—	MD -1.32 (-3 to 0.36)	Low
	CRADI-8, ^a 60 d	47	43	—	MD -0.57 (-3.14 to 2)	Low
	UDI-6, ^a 60 d	47	43	—	MD -5.66 (-9.85 to -1.47)	Low
	PFDI-20, ^a 60 d	47	43	—	MD -7.55 (-13.9 to -1.2)	Low
Hagen et al, ⁷⁸ 2011						
1 RCT	Self-reported, no improvement	7/19 (36.8)	16/21 (76.2)	RR 0.48 (0.26 to 0.91)	-396 (-564 to -69)	Moderate
1 RCT	Prolapse symptom score ^a	17	20	—	MD -3.37 (-6.23 to -0.51)	Moderate
1 RCT	Prolapse interference with everyday life ^a	19	21	—	MD -0.05 (-0.67 to 0.57)	High
1 RCT	Increased bother due to bowel emptying difficulty	11/25 (44.0)	7/15 (46.7)	RR 0.94 (0.47 to 1.90)	-28 (-247 to 420)	Low
1 RCT	Increased bother due to flatus leakage	16/34 (47.1)	18/23 (78.3)	RR 0.68 (0.46 to 0.99)	-250 (-423 to -8)	Moderate
1 RCT	Increased bother due to loose fecal incontinence	5/14 (35.7)	10/10 (100)	RR 0.38 (0.20 to 0.76)	-620 (-800 to -240)	High
1 RCT	Increased bother due to solid fecal incontinence	1/3 (33.3)	1/2 (50)	RR 0.67 (0.08 to 5.54)	-165 (-460 to 1,000)	Low
2 RCTs	POP-Q stage not improved	53/69 (76.8)	55/59 (93.2)	RR 0.83 (0.71 to 0.96)	-158 (-270 to -37)	Very low
1 RCT	ICIQ-UI (change score) ^a	19	20	—	MD -1.79 (-3.68 to 0.1)	High
1 RCT	Mean bladder symptom score ^a	27	20	—	MD -9.22 (-10.68 to -7.76)	Moderate
Ge et al, ⁸¹ 2020						
5 RCTs	Self-reported change in symptoms (better)	—	—	RR 2.90 (1.72 to 4.89)	—	Very low
4 RCTs	Self-reported change in symptoms (same)	—	—	RR 0.7 (0.45 to 1.09)	—	Very low
4 RCTs	Self-reported change in symptoms (worse)	—	—	RR 0.67 (0.22 to 2.03)	—	Very low
5 RCTs	POP-SS ^a	—	—	—	SMD -0.24 (-0.71 to 0.22)	Very low

Studies	Measure	PFMT, n/N (%)	No treatment, n/N (%)	Effect estimate		GRADE ^a
				Relative, ratio (95% CI)	Absolute, per 1,000 (95% CI) unless otherwise indicated	
4 RCTs	POPDI ^a	—	—	—	SMD -0.14 (-0.43 to 0.15)	Very low
4 RCTs	CRADI-8 ^b	—	—	—	SMD -0.03 (-0.16 to 0.11)	Moderate
4 RCTs	UDI-6 ^b	—	-	—	SMD -0.17 (-0.43 to 0.1)	Low
RCTs						
None	—	—	—	—	—	—

Abbreviations: CI, confidence interval; CRADI-8, Colorectal Anal Distress Inventory Questionnaire; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; ICIQ-UI, International Consultation on Incontinence Questionnaire – Urinary Incontinence; MD, mean difference; NICE, National Institute for Health and Care Excellence; POPDI, Pelvic Organ Prolapse Distress Inventory Questionnaire; POP-Q, Pelvic Organ Prolapse Quantification System; POP-SS, Pelvic Organ Prolapse Symptom Score; RR, risk ratio; RCT, randomized controlled trial; SMD, standardized mean difference; UDI-6, Urinary Distress Inventory Short Form Questionnaire.

^aNICE¹ GRADE ratings.

^bLower score is better.

PFMT Versus Other Conservative Treatments

Pessary

Panman et al⁸² compared treatment with a pessary with pelvic floor muscle training. At 12 and 24 months, there were significant differences in symptom improvement with pessary use when compared with pelvic floor muscle training (Table 19). We rated the quality of the evidence (GRADE) as Low, downgrading for risk of bias (Table A17, Appendix 4).

Panman et al⁸² also found a significant difference with pessary for improved sexual function when compared with pelvic floor muscle training at 3, 12, and 24 months (Table 19). We rated the quality of the evidence as Low, downgrading for risk of bias (Table A17, Appendix 4).

Table 19: Summary Results for Pessary Versus PFMT – Improvement of Symptoms (Women, Pelvic Organ Prolapse)

Studies	Measure	PFMT, mean difference (SD)	Pessary, mean difference (SD)	Mean difference (95% CI)
Systematic reviews				
NICE, ⁴⁶ 2021				
1 RCT ⁸²	PFDI, 3 mo	NR	NR	0.50 (-8.79 to 9.79)
	PFDI, 12 mo	NR	NR	4.40 (-4.86 to 13.66)
	PFDI, 24 mo	NR	NR	6.90 (-1.31 to 15.11)
	CRADI, 3 mo	NR	NR	2.00 (-1.83 to 5.83)
	CRADI, 12 mo	NR	NR	1.10 (-2.67 to 4.87)
	CRADI, 24 mo	NR	NR	2.10 (-1.27 to 5.47)
	UDI, 3 mo	NR	NR	-3.60 (-8.21 to 1.01)
	UDI, 12 mo	NR	NR	-0.50 (-5.05 to 4.05)
	UDI, 24 mo	NR	NR	-1.00 (-5.04 to 3.04)
	POPDI, 3 mo	NR	NR	2.90 (-0.62 to 6.42)
	POPDI, 12 mo	NR	NR	4.10 (0.64 to 7.56)
	POPDI, 24 mo	NR	NR	4.70 (1.61 to 7.79)
	Sexual function (PISQ), 3 mo	NR	NR	2.70 (0.87 to 4.53)
	Sexual function (PISQ), 12 mo	NR	NR	2.60 (0.88 to 4.32)
	Sexual function (PISQ), 24 mo	NR	NR	1.30 (0.25 to 2.35)
RCTs				
None	—	—	—	—

Abbreviations: CI, confidence interval; CRADI, Colorectal Anal Distress Inventory; mo, months; NR, not reported; PFDI, Pelvic Floor Distress Inventory; PFMT, pelvic floor muscle training; PISQ, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; POPDI, Pelvic Organ Prolapse Distress Inventory; SD, standard deviation; UDI, Urogenital Distress Inventory.

Source: Data from Ontario Health.³⁰

Quality of Life

PFMT Versus No Treatment

Women who underwent pelvic floor muscle training had significantly better quality of life scores in comparison with women who did not undergo treatment (Table 20).

NICE¹ downgraded for risk of bias and rated the quality of the evidence as Moderate (Table A16, Appendix 4).

Table 20: Summary Results for PFMT Versus No Treatment – Quality of Life (Women, Pelvic Organ Prolapse)

Studies	Measure	PFMT, n	No treatment, n	Mean difference (95% CI)	GRADE ^a
Systematic reviews					
NICE, ¹ 2021					
Hagen et al, ⁷⁸ 2011					
1 RCT	Ditrovie quality of life score	27	20	-0.95 (-1.57 to 0.34)	Moderate
RCTs					
None	—	—	—	—	—

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; PFMT, pelvic floor muscle training; NICE, National Institute for Health and Care Excellence; RCT, randomized controlled trial.

^aNICE¹ GRADE ratings.

PFMT Versus Other Conservative Treatments

Pessary

Panman et al⁸² found no significant difference between quality of life after pessary use alone when compared with pelvic floor muscle training at 3, 12, or 24 months (Table 21).

We rated the quality of the evidence as Low, downgrading for risk of bias (Table A17, Appendix 4).

Table 21: Summary Results for Pessary Versus PFMT – Quality of Life (Women, Pelvic Organ Prolapse)

Studies	Measure	PFMT, n	Pessary, n	Mean difference (95% CI)
Systematic reviews				
NICE, ⁴⁶ 2021				
1 RCT ⁸²	PFDI, 3 mo	NR	NR	1.30 (-6.25 to 8.85)
	PFDI, 12 mo	NR	NR	-4.20 (-11.28 to 2.88)
	PFDI, 24 mo	NR	NR	2.10 (-4.48 to 8.68)
RCTs				
None	—	—	—	—

Abbreviations: CI, confidence interval; mo, months; NR, not reported; PFDI, Pelvic Floor Distress Inventory; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

Source: Data from Ontario Health.³⁰

Satisfaction

PFMT Versus No Treatment

Hagen et al⁷⁸ reported a significantly better score for women's satisfaction with pelvic organ prolapse treatment for women who received pelvic floor muscle training compared with those who did not undergo treatment (or inactive control) (Table 22).

NICE¹ downgraded for risk of bias and rated the quality of the evidence as Moderate (Table A16, Appendix 4).

Table 22: Summary Results for PFMT Versus No Treatment – Satisfaction (Women, Pelvic Organ Prolapse)

Studies	Measure	PFMT, n	No treatment, n	Mean difference (95% CI)	GRADE ^a
Systematic reviews					
NICE, ¹ 2021					
Hagen et al, ⁷⁸ 2011					
1 RCT	Satisfaction with treatment, scored from 0–10, lower is better	27	20	-3.22 (-3.79 to -2.65)	Moderate
RCTs					
None	—	—	—	—	—

Abbreviations: CI, confidence interval; GRADE, *Grading of Recommendations Assessment, Development, and Evaluation*; PFMT, pelvic floor muscle training; NICE, National Institute for Health and Care Excellence; RCT, randomized controlled trial.

^aNICE¹ GRADE ratings.

PFMT Versus Other Conservative Treatments

No studies were identified.

Complications

PFMT Versus No Treatment

No studies were identified.

PFMT Versus Other Conservative Treatments

Pessary

Panman et al⁸² found a significant difference favouring pelvic floor muscle training over pessary use on adverse events at 24 months in people with pelvic organ prolapse (Table 23).

We rated the overall quality of evidence (GRADE) as Very low, downgrading for risk of bias and imprecision (Table A17, Appendix 4).

Table 23: Summary Results for Pessary Versus PFMT – Complications (Women, Pelvic Organ Prolapse)

Studies	Measure	PFMT, n/N (%)	Pessary, n (%)	RR (95% CI)
Systematic reviews				
NICE, ⁴⁶ 2021				
1 RCT ⁸²	Adverse events ^a	0/57 (0)	21/35 (60)	0.02 (0.00 to 0.37)
	Vaginal discharge	0	14	
	Increase of urinary incontinence	0	5	
	Irritation or erosion of vaginal walls	0	10	
RCTs				
None	—	—	—	—

Abbreviations: CI, confidence interval; PFMT, pelvic floor muscle training; NICE, National Institute for Health and Care Excellence; RCT, randomized controlled trial; RR, risk ratio.

^aMore than 1 option is possible.

Source: Data from Ontario Health.³⁰

Men

We did not identify any studies that examined the use of pelvic floor muscle training with men with pelvic organ prolapse (e.g., rectal prolapse).

Ongoing Studies

We are aware of the following ongoing studies that have potential relevance to this review:

- The Effect of Pelvic Floor Muscle Training for Urinary Incontinence in Nepalese Women <https://clinicaltrials.gov/study/NCT05618886>
- Effect of Pelvic Floor Muscle Training on Urinary Incontinence Reports in Obese Women Undergoing a Low Calorie Diet <https://clinicaltrials.gov/study/NCT04159467>
- Additional Effects of Aerobic and Resistance Exercises to Pelvic Floor Muscle Training After Radical Prostatectomy <https://clinicaltrials.gov/study/NCT06126874>
- Comparison of Pelvic Floor Therapy and Yoga on Stress Urinary Incontinence <https://clinicaltrials.gov/study/NCT05253898>

Discussion

Stress Urinary Incontinence

The evidence showed that pelvic floor muscle training was effective in improving stress urinary incontinence symptoms for women.¹ Kenton et al⁶² noted that both the pessary and pelvic floor muscle training groups had clinically meaningful within-group improvement on every symptom measure; however, improvements did not differ significantly between the 2 treatment arms. Given this, Kenton et al⁶² concluded that both pelvic floor muscle training and pessaries have a clinically important role in the treatment of stress urinary incontinence.⁶² Patients may see symptom improvement with either treatment modality, and individual patient characteristics and preferences can inform decisions

among nonsurgical treatment options.⁶² For men, there was a large amount of heterogeneity in methodology and findings.³⁴ Johnson et al³⁴ concluded that results from the body of evidence were likely imprecise, because most studies were small and had few participants. In addition, the findings may not be generalizable to men who underwent procedures other than radical prostatectomy (i.e., transurethral resection of the prostate).³⁴

Fecal Incontinence

Pelvic floor muscle training was found to be effective for women with loose fecal incontinence or flatus leakage – a finding which provided support for the NICE recommendation for pelvic floor muscle training for this clinical population¹; however, there was uncertainty about the effectiveness of pelvic floor muscle training for solid fecal incontinence, since it was found to be uncommon in women with pelvic organ prolapse. Thus, no recommendation was made by NICE committee with respect to solid fecal incontinence in women.¹

Pelvic floor muscle training was not found to be more effective than standard care in improving symptoms; however, Forte et al⁴⁷ noted that drawing conclusions for fecal incontinence from the findings of the studies was made difficult by the fact that different protocols were used – timing, intensity, type, and duration of pelvic floor muscle training and type of treatment for standard care (e.g., dietary fiber and stool-modifying drugs in 1 study and advice in the other). Forte et al⁴⁷ also noted that baseline patient information, etiology, and short-term follow-up were incompletely reported by studies included in their review.

Pelvic Organ Prolapse

The body of evidence included trials with people for whom pelvic organ prolapse surgery was indicated (i.e., with more severe symptoms that may respond less to pelvic floor muscle training).¹ Because people undergoing treatment with a pessary had a significantly greater reduction in prolapse-specific symptoms compared with people in the pelvic floor muscle training group, Panman et al⁸² suggested that people with typical prolapse symptoms benefit more from pessary treatment than from pelvic floor muscle training, which is plausible given that pessaries redress prolapse directly. Panman et al⁸² also found that more people reported 1 or more complications with pessary treatment compared with people undergoing pelvic floor muscle training.⁸² Symptom improvement was reported most in women with prolapse that did not extend below the hymen (stage 1 or 2 pelvic organ prolapse stage measured by the Pelvic Organ Prolapse Quantification), and as such, the NICE recommendation was limited to women with stage 1 or 2 pelvic organ prolapse.¹ The NICE expert committee agreed that subjective measures are particularly important as they may indicate participants' perceptions of success which may subsequently benefit their quality of life.¹

Comment Regarding Blinding in Trials of PFMT

Most studies included in this HTA were at high risk of performance bias because the nature of pelvic floor muscle training often meant that it would have been impossible to blind the participants and the providers of the treatments in each arm. It is highly unlikely that double blinding can be achieved due to the nature of this intervention.

Strengths and Limitations

Strengths of our analysis:

- We leveraged existing research and expanded the clinical population of interest (stress urinary incontinence postprostatectomy for men and fecal incontinence for men and women).
- We incorporated an analysis of quantitative preference evidence.

Limitations of our analysis:

- No studies with eHealth, i.e., internet-delivered pelvic floor muscle training, were included; however, eHealth is a rapidly expanding area in pelvic floor muscle training for pelvic organ prolapse, stress urinary incontinence, and fecal incontinence. As more studies on this topic are published in the future, we may expand the comprehensiveness of this HTA.

Conclusions

Stress Urinary Incontinence

Women

For women with stress urinary incontinence:

- In comparison with no treatment, pelvic floor muscle training
 - Likely results in a large reduction in symptoms
 - May improve quality of life, but the evidence is very uncertain
 - Likely results in a large increase in satisfaction
- In comparison with treatment with a pessary, pelvic floor muscle training
 - May result in little to no difference in symptoms
 - May result in little to no difference in satisfaction
- In comparison with treatment with a pessary, pelvic floor muscle training in addition to treatment with a pessary
 - May result in little to no difference in symptoms
 - May result in little to no difference in satisfaction
- In comparison with electrical stimulation therapy, pelvic floor muscle training
 - May have little to no effect on symptoms, but the evidence is very uncertain
 - May have little to no effect on quality of life, but the evidence is very uncertain
- In comparison with electrical stimulation therapy, pelvic floor muscle training with biofeedback
 - May improve quality of life, but the evidence is very uncertain

- In comparison with electrical stimulation therapy, pelvic floor muscle training in addition to electrical stimulation
 - May have little to no additional effect on symptoms, but the evidence is very uncertain
 - May have little to no additional effect on quality of life, but the evidence is very uncertain
- In comparison with magnetic stimulation therapy, pelvic floor muscle training
 - May have little to no effect on symptoms, but the evidence is very uncertain
 - May have little to no effect on complications, but the evidence is very uncertain
- In comparison with treatment with a vaginal cone, pelvic floor muscle training
 - May have little to no effect on symptoms, but the evidence is very uncertain
 - May result in little to no difference (without biofeedback) or no difference (with biofeedback) in quality of life

For prenatal women with stress urinary incontinence or fecal incontinence:

- In comparison with usual care, pelvic floor muscle training:
 - May improve quality of life, but the evidence is very uncertain

Men

For men with stress urinary incontinence postprostatectomy:

- In comparison with no treatment, sham treatment, or verbal/written instructions, pelvic floor muscle training
 - May have little to no effect on symptom improvement, but the evidence is very uncertain
 - May have little to no effect on quality of life, but the evidence is very uncertain
 - May show little to no difference in the occurrence of complications, but the evidence is very uncertain
- In comparison with no treatment, sham treatment, or verbal/written instructions, pelvic floor muscle training with biofeedback
 - May result in little to no difference in symptom improvement
 - May show little to no difference in the occurrence of complications but the evidence is very uncertain

Fecal Incontinence

For men or women with fecal incontinence:

- In comparison with standard care, pelvic floor muscle training
 - May have little to no effect on symptoms, but the evidence is very uncertain

Pelvic Organ Prolapse

For women with pelvic organ prolapse:

- In comparison with no treatment, pelvic floor muscle training
 - Likely reduces symptom severity
 - Likely improves quality of life
 - Likely improves patient satisfaction
- In comparison with treatment with a pessary, pelvic floor muscle training
 - May not reduce symptom severity
 - May not improve sexual function
 - May have fewer associated complications, but the evidence is very uncertain

Economic Evidence

Research Question

What is the cost-effectiveness of pelvic floor muscle training compared with no treatment or conservative usual care for the treatment of people with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse?

Methods

Economic Literature Search

Using the same search criteria as those used in the NICE systematic review,¹ with the exception of date range (NICE search date range: January 1, 1980, to February 2021), we performed an economic literature search on June 6, 2023, to retrieve studies published since January 1, 2021. We used the Ovid interface in the following databases: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews. We also used the EBSCOhost interface to search the Cumulative Index to Nursing & Allied Health Literature (CINAHL).

Because the 2021 NICE systematic review scope was limited to studies with women,¹ a supplemental search was run in the same databases listed above and in the National Health Service Economic Evaluation Database (NHS EED), using filters^{48,49} to capture studies with other genders and expanded concept scopes (e.g., prostatectomy and transgender) published from January 1, 1980, to June 6, 2023. In addition, we screened the list of studies excluded from the 2021 NICE review to identify any studies that included men.

Database auto-alerts in MEDLINE, Embase, and CINAHL were monitored until August 2023. We also performed a targeted grey literature search following a standard list of websites developed internally, which includes the International HTA Database and the Tufts Cost-Effectiveness Analysis Registry (see Appendix 1 for our literature search strategies, including all search terms).

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text papers
- Studies published since January 1, 2010 (because costs from earlier economic evaluations would be outdated; thus, their findings may be less applicable)
- Cost–benefit, cost-effectiveness, or cost–utility analyses

Exclusion Criteria

- Reviews, editorials, case reports, commentaries, and abstracts, conferences abstracts, letters
- Cost analyses and cost-minimization analyses

Participants

Inclusion Criteria

- People (≥ 12 years) diagnosed with stress urinary incontinence, fecal incontinence or pelvic organ prolapse

Exclusion Criteria

- People ≤ 11 years of age
- People with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse not associated with pelvic floor dysfunction (e.g., urinary incontinence due to a neurological condition)

Interventions

Inclusion Criteria

- Supervised pelvic floor muscle training for treatment (such as but not limited to Kegel exercises) with or without adjunct (e.g., biofeedback, weighted vaginal cones, and electrical or neuromuscular stimulation) or other conservative treatment (e.g., pessary)

Exclusion Criteria

- Pelvic floor muscle training for prevention
- Unsupervised and unguided pelvic floor muscle training (e.g., pamphlets, DVDs, online)

Comparators

Inclusion Criteria

- Control (i.e., no active treatment)
- Other conservative treatment (e.g., pessary)

Exclusion Criteria

- Surgeries
- Any treatment pathway that includes surgical treatment
- Another type of pelvic floor muscle training

Outcome Measures

- Costs
- Health outcomes (e.g., quality-adjusted life-years [QALYs])
- Incremental costs
- Incremental effectiveness
- Incremental cost-effectiveness ratios

Literature Screening

A single reviewer conducted an initial screening of titles and abstracts and then obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. The reviewer then examined the full-text articles to identify studies eligible for inclusion. The reviewer also consulted content experts for any additional relevant studies not identified through the search.

Data Extraction

Results of economic review were stratified by sex and type of pelvic floor dysfunction. We extracted relevant data on study characteristics and outcomes to collect information about the following:

- Source (e.g., citation information, study type)
- Methods (e.g., study design, analytic technique, perspective, time horizon, population, intervention[s], comparator[s])
- Outcomes (e.g., health outcomes, costs, incremental cost-effectiveness ratios [ICERs])

Study Applicability and Limitations

We determined the usefulness of each identified study for decision-making by applying a modified quality appraisal checklist for economic evaluations originally developed by the National Institute for Health and Care Excellence (NICE) in the United Kingdom to inform the development of clinical guidelines.⁸³ We modified the wording of the questions to remove references to guidelines and to make it specific to Ontario. Next, we separated the checklist into 2 sections. In the first section, we assessed the applicability of each study to the research question (directly, partially, or not applicable). In the second section, we assessed the limitations (minor, potentially serious, or very serious) of the studies that we found to be directly applicable.

Results

Economic Literature Search

The database search of the economic literature yielded 409 citations published between May 1995 and May 2023, including grey literature searches and after duplicates were removed. We also identified 12 studies from the reference lists of review identified during scoping.^{30,84} In total, we identified 6 economic analyses in 5 papers.^{82,85-88} See Appendix 2 for a list of selected studies excluded after full-text review. Figure 2 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for the economic literature search.

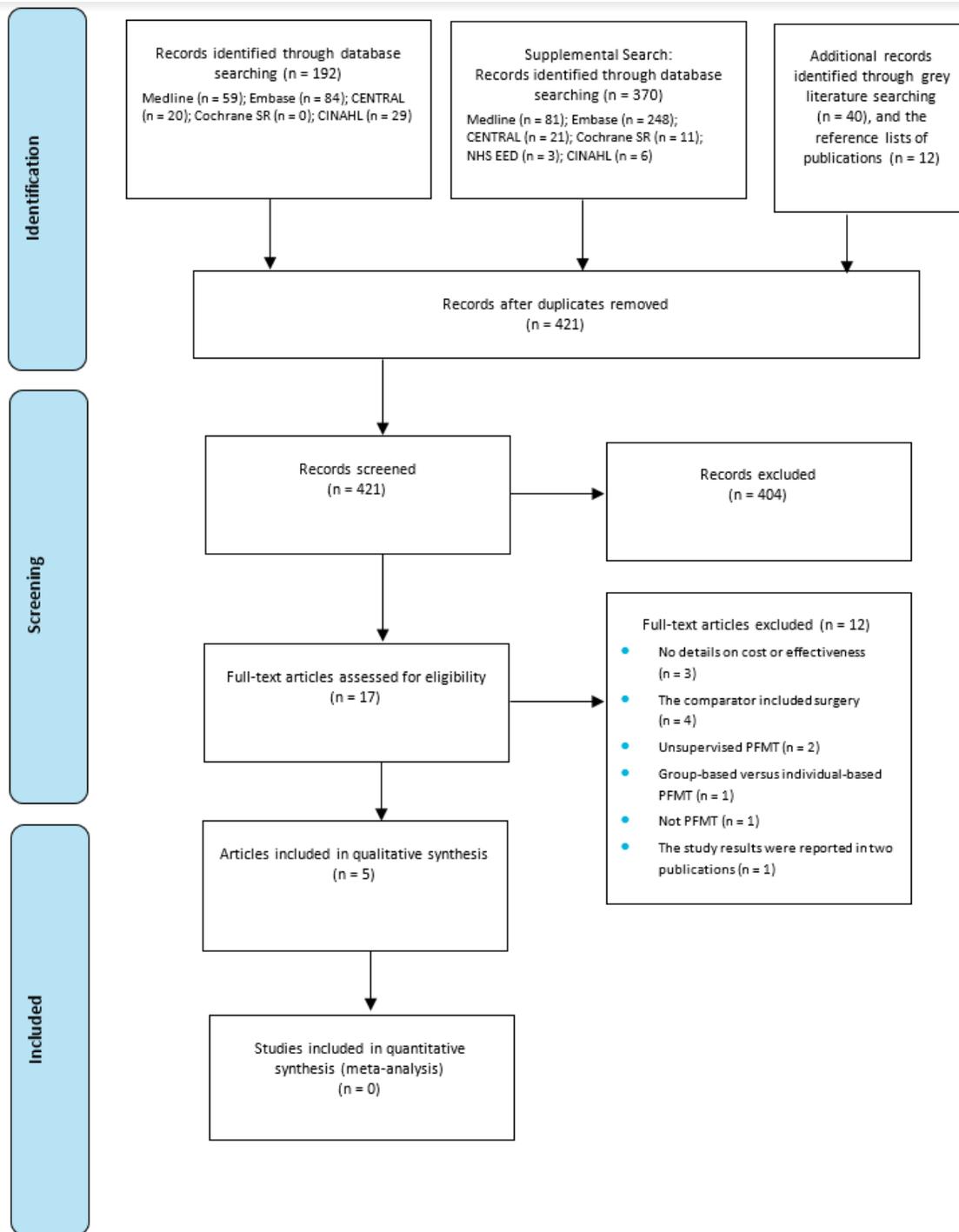


Figure 2: PRISMA Flow Diagram – Economic Systematic Review

PRISMA flow diagram showing the economic search strategy. The database search of the economic literature yielded 409 citations published between May 1995 and May 2023, including grey literature searches and after duplicates were removed. We also identified 12 studies from the reference lists of earlier publications.^{30,84} We screened the abstracts of the 409 identified studies and excluded 392. We assessed the full text of 17 articles and excluded a further 12. In the end, we included 5 articles (6 studies) in the qualitative synthesis.

Abbreviations: NICE, National Institute for Health and Care Excellence; PFMT, pelvic floor muscle training; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.⁵¹

Overview of Included Economic Studies

We included 6 cost–utility analyses that evaluated pelvic floor muscle training in 3 clinical populations (women with stress urinary incontinence, women with pelvic organ prolapse, and men with urinary incontinence after prostate surgery).^{82,85–88} We did not identify any economic studies for fecal incontinence. Among the 6 included analyses, 2 were model-based economic evaluations,^{85,86} and 4 were economic evaluations conducted alongside randomized controlled trials.^{82,87,88} The studies were conducted in the United Kingdom,⁸⁸ the Netherlands,^{82,87} Canada,⁸⁶ and the United States.⁸⁵ We present the study design, populations, outcomes, time horizons, and study results in Table 24.

Stress Urinary Incontinence

Women

Chang et al⁸⁵ conducted a model-based cost–utility analysis of 8 treatment strategies for women with stress urinary incontinence from the US health care system perspective over a 2-year time horizon. Each strategy included a treatment pathway, from the index treatment to subsequent treatments. We excluded 5 strategies with surgical interventions from our review and focused on the 3 strategies with conservative treatments only: pelvic floor muscle training, treatment with a pessary, and no treatment. Although some information is provided about surgical treatment pathways – Chang et al⁸⁵ stated that pathways “include management in the event of continued stress urinary incontinence after the index surgery” – no information was provided about subsequent treatment for pathways with pelvic floor muscle training and pessary as the index treatments. For the no-treatment strategy, subsequent treatments would be provided when necessary. We judged that these treatment pathways likely did not include the surgical treatment; if surgical treatments are part of treatment pathways when no treatment or initial conservative treatments (pelvic floor muscle training or treatment with a pessary) were not successful, the total costs would be much higher than those reported, which ranged from \$1,053 to \$1,392 (the costs of surgical treatments were approximately \$5,000).

Treatment success probabilities were similar for both pelvic floor muscle training (success probability, $p = .53$) and treatment with a pessary (success probability, $p = .514$). Compared with treatment with a pessary, pelvic floor muscle training was cost-effective and yielded an ICER of \$22,729 USD (US dollars) per QALY gained. Compared with pelvic floor muscle training or treatment with a pessary, the no-treatment strategy was associated with higher costs and lower effectiveness in QALYs.

Simpson et al⁸⁶ conducted a model-based cost–utility analysis to evaluate 5 treatment strategies for women with stress urinary incontinence. The study was conducted from a health system perspective. Because costs were obtained in Canada, converted into US dollars, and were reported in both US and Canadian dollars, we expect that the findings from the analysis are applicable to Canada and the United States.

For the no-treatment strategy, Simpson et al⁸⁶ assigned zero cost and no chance of cure. For the pessary treatment strategy, no subsequent treatment was included if the initial treatment was not successful; however, for treatment with Impressa (a disposable tampon device) and Uresta (a self-fitted intravaginal incontinence device) strategies, subsequent treatment was included if the initial treatment was not successful.

The pelvic floor muscle training strategy was associated the highest QALYs and highest costs (note that both the initial and subsequent treatments contributed to the cost-effectiveness results). Pelvic floor

muscle training was the optimal strategy at a willingness-to-pay of \$50,000 USD per QALY gained (\$1.00 CAD = \$ 0.74 USD in 2017) of 5 strategies⁸⁶; however, net monetary benefit values for the different strategies had considerable overlap at this willingness-to-pay value. This indicates that there is some uncertainty associated with determining the optimal strategy with the highest net monetary benefit.

We calculated the cost-effectiveness for comparisons of interest (pelvic floor muscle training compared with no treatment and pelvic floor muscle training compared with pessary): the incremental cost-effectiveness ratios were \$9,794 CAD per QALY gained, for pelvic floor muscle training versus no treatment ($(\$823.65 - \$0) \div (0.8941 - 0.81) = \$9,794$), and \$20,738 CAD per QALY gained, for pelvic floor muscle training versus pessary ($(\$823.65 - \$75) \div (0.8941 - 0.8580) = \$20,738$).

Men

We did not find any studies on stress urinary incontinence specifically in men, but we found 2 studies that focused on urinary incontinence, of which stress urinary incontinence is a subtype. Glazener et al⁸⁸ conducted 2 randomized controlled trials to evaluate pelvic floor muscle training plus lifestyle advice versus lifestyle advice only in men with urinary incontinence following radical prostatectomy (usually for prostate cancer) or following transurethral resection of the prostate (usually for benign prostatic hypertrophy) in the United Kingdom.⁸⁸ In these 2 analyses, most participants (> 50%) had diagnosed stress urinary incontinence at baseline, although the randomized controlled trials also included people with urgency urinary incontinence after prostate surgeries.⁸⁸ Economic evaluations were also conducted alongside these 2 trials. Glazener et al⁸⁸ conducted both analyses from the National Health Service (NHS) perspective and the societal perspective (e.g., including the costs of time-off and travel).

In the trial involving men who had radical prostatectomy,⁸⁸ 411 men were randomly assigned to 2 groups (pelvic floor muscle training: n = 205; control: n = 206). The study duration was 1 year. Both groups had the same QALYs (0.86 QALYs) over 1 year. After adjusted baseline EQ-5D utility, the difference in QALYs between the 2 groups was 0.002 (95% CI -0.023 to 0.027), slightly favoring pelvic floor muscle training. The pelvic floor muscle training group had higher costs than the control group. On average, the pelvic floor muscle training program cost £198.30 pounds sterling (GBP) per person for 4 sessions with 1-to-1 training over 3 months, and this cost was the main driver of the cost difference between the 2 groups (mean difference £181.02 GBP). Results from the NHS perspective showed that, compared with the control, pelvic floor muscle training yielded an ICER of £90,510 GBP per QALY gained, which is higher than the commonly used willingness-to-pay value in the United Kingdom (£20,000 to £30,000 GBP per QALY gained). Results from the societal perspective showed that, in comparison with the control group, the pelvic floor muscle training group yielded cost savings (mean adjusted savings: £588.23 GBP per person). This cost savings was largely due to fewer workdays taken off by participants in the pelvic floor muscle training group than by the control group (adjusted cost difference -£694.77 GBP [95% CI -1388.71 to -0.83]). However, Glazener et al⁸⁸ suggested that “these results have to be interpreted cautiously” because the savings were driven by reduced workdays.

In a trial⁸⁸ with 442 men randomly assigned to pelvic floor muscle training (n = 220) and control (n = 222) after transurethral resection of the prostate, the 1-year QALYs were 0.78 and 0.82, respectively. After adjusting for minimization factors and baseline EQ-5D utility, the difference in QALYs was very small (-0.00003 [95% CI -0.026 to 0.026]), slightly favoring the control. In the analysis from the UK NHS perspective, pelvic floor muscle training was associated with higher costs (mean adjusted difference for total cost: £208.88 GBP), and the cost of pelvic floor muscle training program was the main driver. In the analysis from the societal perspective, the pelvic floor muscle training group was found to have a higher

number of days taken off work than the control group (adjusted cost difference £279.32 GBP [95% CI –61.62 to 620.28]), and the pelvic floor muscle training group was also associated with higher total costs (mean difference: £419.50 GBP) from both the cost of the pelvic floor muscle training program and the cost of taking workdays off. Therefore, from both perspectives, the pelvic floor muscle training strategy was dominated by the control.

Fecal Incontinence

Adults

No studies were identified in men or women.

Pelvic Organ Prolapse

Women

Panman et al⁸⁷ conducted a cost–utility analysis alongside a randomized controlled trial to compare pelvic floor muscle training and watchful waiting for women older than 55 years with symptomatic mild prolapse in the Netherlands. This study included 287 women (pelvic floor muscle training: n = 145; and watchful waiting: n = 142), and the trial duration was 24 months. The average total direct medical costs per person were €330 euros (EUR) and €91 EUR for the pelvic floor muscle training and watchful waiting groups, respectively. The cost of physical therapy for the pelvic floor muscle training group (€254 EUR) was the main driver of the cost difference between the 2 groups. Panman et al did not report longitudinal utilities and total QALYs, but stated that, “with regard to the utility scores, both groups lost QALYs (0.067 in the watchful waiting group and 0.061 in the PFMT group).”⁸⁷ While it was unclear how the QALYs or QALY loss was estimated, the difference in QALY loss between the 2 groups was small (0.067 – 0.061 = 0.006). Compared with watchful waiting, pelvic floor muscle training yielded an ICER of €31,983 EUR per QALY gained. Probabilistic sensitivity analysis, conducted by running 10,000 simulations, showed that there was a high level of uncertainty associated with the cost-effectiveness results, with 45% of the simulations showing that pelvic floor muscle training was less effective and more costly.

Panman et al⁸² also conducted a cost–utility analysis alongside a randomized controlled trial to compare pelvic floor muscle training and pessaries for women older than 55 years with symptomatic advanced prolapse in the Netherlands; the trial duration was 24 months. The average total direct medical costs per person were \$437 USD and \$309 USD for the pelvic floor muscle training and pessary groups, respectively. The cost of pessaries and associated doctor visits were \$202 USD per person, and the cost of pelvic floor muscle training was \$324 USD. Other costs, such as doctor visits, pads, and other prolapse treatments, were comparable between 2 groups. Longitudinal utilities and total QALY values were not reported, but “both treatment groups lost QALYs over the 2-year period, although the loss of QALYs was slightly lower in the pessary group (0.024 in the pessary group and 0.065 in the pelvic floor muscle training group).”⁸² Pelvic floor muscle training was dominated by treatment with pessaries; pelvic floor muscle training had higher costs and greater QALYs lost. These findings are considered to be robust – probabilistic sensitivity analysis showed that 95% of bootstrap replications found treatment with pessary to be more effective and less costly than pelvic floor muscle training.

Men

No studies were identified.

Table 24: Results of Economic Literature Review – Summary

Author, year; country	Study and analysis characteristics	Population	Interventions ^a	Results		
				Health outcomes	Costs	Cost-effectiveness
Urinary incontinence						
Chang et al, ⁸⁵ 2022; United States	Cost–utility analysis, decision model Perspective: US health care system Time horizon (discount rate): 2 y (NA)	Women with stress urinary incontinence Age NR	Intervention ^a : PFMT Control ^a : No treatment Pessary	Total, mean PFMT: 1.765 No treatment: 1.500 Pessary: 1.757	(in 2019 USD) Physical therapy, per visit: \$104 Total, mean: PFMT: \$1,241 No treatment: \$1,392 Pessary: \$1,053	(in 2019 USD) PFMT vs no treatment: PFMT dominated (higher QALYs and lower cost) PFMT vs. pessary: ICER \$22,729 Probabilistic analysis: NR
Simpson et al, ⁸⁶ 2019; Canada	Cost–utility analysis, decision tree model Perspective: Health care system (payer agnostic ^b) Time horizon (discount rate): 1 y (NA)	Women with stress urinary incontinence, ≥ 18 y, with additional criteria ^c	Intervention: PFMT ^d Control: No treatment Pessary (traditional) ^e Uresta ^{d,f} (self-fitted) Impressa ^d (self-fitted, disposable)	Total, mean ^g : No treatment: 0.8100 Pessary: 0.8580 Impressa: 0.8863 PFMT: 0.8941	(in 2017 CAD ^h) PFMT program, 4–6 sessions, mean (SD): \$715 (142.50) Total, mean ^g : No treatment: \$0 Pessary: \$75.00 Impressa: \$469.34 PFMT: \$823.65	(in 2017 CAD ^h) Sequential ICER ^g : No treatment: — Pessary: \$1,563 Impressa: \$13,934 ⁱ PFMT: \$45,377 WTP \$67,568 (\$50,000 USD)—PFMT is optimal Probabilistic analysis: Results consistent with the reference case; no CEAC
Glazener et al, ⁸⁸ 2011; United Kingdom	Cost–utility analysis alongside randomized controlled trial Perspective: UK National Health Service and societal Time horizon (discount rate): 1 y (NA)	Men with urinary incontinence, 6 wk after radical prostatectomy (N = 411) ^j PFMT : n = 205 Control: n = 206 Age (mean) PFMT: 62.4 y Control: 62.3 y	Intervention: PFMT with lifestyle advice Control: Standard care with lifestyle advice	Total (EQ-5D), mean (SD) PFMT: 0.86 (0.19) Control: 0.86 (0.16) Adjusted mean difference (95% CI): 0.002 (–0.023 to 0.027) ^{k,l}	(in 2008 GBP) PFMT program, 4 sessions, mean (SD): £198.30 (63.89) UK National Health Service Total, mean (SD): PFMT: £556.72 (396.07) Control: £378.99 (399.45) Adjusted mean difference (95% CI): £181.02 (107.06 to 254.97) Societal^m PFMT program, mean (SD), 4 sessions: £132.70 (43.43) Total, mean (SD):	(in 2008 GBP) UK National Health Service ICER: £90,510 ⁱ Probabilistic analysis: For PFMT, WTP £20,000—19.2% probability WTP £30,000—27.3% probability Societal^m PFMT dominated control (on average, more effective and less costly) Probabilistic analysis: For PFMT, WTP £20,000—89.4% probability

Author, year; country	Study and analysis characteristics	Population	Interventions ^a	Results		
				Health outcomes	Costs	Cost-effectiveness
					PFMT: £1,508.63 (2,802.37) Control: £2,209.10 (4,835.12) Adjusted mean difference (95% CI): -£588.23 (-1,329.83 to 153.37)	WTP £30,000—83.7% probability
Glazener et al, ⁸⁸ 2011; United Kingdom	Cost-utility analysis alongside randomized controlled trial Perspective: UK National Health Service and societal Time horizon (discount rate): 1 y (NA)	Men with urinary incontinence, 6 wk after transurethral resection of the prostate (N = 442) ⁿ PFMT : n = 220 Control: n = 222 Age (mean) PFMT: 68.2 y Control: 67.9 y	Intervention: PFMT with lifestyle advice Control: Standard care with lifestyle advice	Total EQ-5D QALYs, mean (SD) PFMT: 0.78 (0.24) Control: 0.82 (0.22) Adjusted mean difference (95% CI): -0.00003 (-0.026 to 0.026) ^o	(in 2008 GBP) UK National Health Service PFMT program, mean (SD), 4 sessions: £174.47 (82.89) Total, mean (SD): PFMT: £492.59 (355.95) Control: £284.81 (315.07) Adjusted mean difference (95% CI): £208.88 (146.69 to 271.07) Societal^m PFMT program, mean (SD), 4 sessions: £78.39 (38.18) Total, mean (SD): PFMT: £983.81 (2,626.28) Control: £566.05 (1,284.97) Adjusted mean difference (95% CI): £419.50 (53.67 to 785.31)	(in 2008 GBP) UK National Health Service PFMT dominated by control Probabilistic analysis: For PFMT, WTP £20,000 — 20.0% probability WTP £30,000 — 29.4% probability Societal^m PFMT dominated by control Probabilistic analysis: For PFMT, WTP £20,000—11.2% probability WTP £30,000—17.3% probability
Pelvic organ prolapse						
Panman et al, ⁸⁷ 2017; Netherlands	Cost-utility analysis alongside randomized controlled trial Perspective: NR ^p Time horizon (discount rate): 2 y (NR)	Women (≥ 55 y) with symptomatic mild ^q prolapse (N = 287) PFMT: n = 145 Control: n = 142 Age, mean PFMT: 64.5 y Control: 64.0 y	Intervention: PFMT Control: Watchful waiting	QALY loss ^r PFMT: 0.061 Control: 0.067	(in 2013 EUR) Physical therapy: €254 Total, mean: PFMT: €330 Watchful waiting: €91 Mean difference (95% CI): €239 (€161 to €319)	(in 2013 EUR) ICER (95% CI): €31,983 (-€76,652 to €88,078) Probabilistic analysis (CEAC): For PFMT, 55% indicated more effective and more costly, and 45% indicated less effective and more costly
Panman et al, ⁸² 2016; Netherlands	Cost-utility analysis alongside randomized controlled trial	Women (≥ 55 y) with symptomatic advanced ^s prolapse (N = 162)	Intervention: PFMT Control:	QALY loss ^{t,u} PFMT: 0.065 Pessary: 0.024	(in 2015 USD) PFMT program: \$324 Total, mean:	PFMT (higher costs and greater QALY loss) ^r dominated by pessary Probabilistic analysis:

Author, year; country	Study and analysis characteristics	Population	Interventions ^a	Results		
				Health outcomes	Costs	Cost-effectiveness
	Perspective: NR ^o	PFMT (n = 80) Pessary (n = 82)	Pessary		PFMT: \$437 Pessary: \$309	Findings consistent with the reference case; pessary – greater effectiveness and lower cost in 95% of bootstrap replications
	Time horizon (discount rate): 2 y (NR)	Age, mean PFMT: 65.6 y Pessary: 64.9 y			Mean difference (95% CI): \$128 (\$27 to \$236)	

Abbreviations: CAD, Canadian dollars; CEAC, cost-effectiveness acceptability curve; CI, confidence interval; EQ-5D, EuroQoL 5 Dimension; EUR, euro; GBP, pounds sterling; ICER, incremental cost-effectiveness ratio; mo, month; NA, not applicable; NR, not reported; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; QALY, quality-adjusted life-year; SD, standard deviation; SF-6D, Short-Form 6-dimension; UK, United Kingdom; US, United States; USD, US dollars; wk, week; WTP, willingness to pay, y, years.

General note: Values in the *Health outcomes* column are in units of QALY per person, values in the *Costs* column are in units of currency per person, and values in the *Cost-effectiveness* column are in units of currency per QALY.

^aBased on our definition (i.e., original paper may have considered PFMT as the intervention). Only information relevant to this HTA is included (i.e., surgical strategies are excluded).

^bSimpson et al⁸⁶ stated “We used a health system perspective, including all direct health care expenditures irrespective of payer.”⁸⁶

^cSimpson et al⁸⁶ specified as additional criteria that “patients required sufficient manual dexterity to perform self-management of all modalities.”

^dAs initial treatment in the treatment pathway. If initial treatment is unsuccessful, women switch to another nonsurgical treatment.

^eNo further treatment if initial treatment is unsuccessful.

^fUresta (mean QALY per person: 0.8818, mean cost per person: \$411.17 [in 2017 CAD]) excluded from the results because it was the extendedly dominant strategy (ICER: Uresta vs pessary \$14,149; Impresa vs Uresta: \$12,757).⁸⁶

^gWith respect to PFMT – Health outcome mean differences: PFMT vs. Impresa, 0.0078; PFMT vs no treatment, 0.0841; PFMT vs pessary, 0.0361. Cost mean differences: PFMT vs. Impresa: \$354.31; PFMT vs no treatment, \$823.65; PFMT vs pessary: \$748.65. ICERs: PFMT vs Impresa, \$45,377; PFMT vs no treatment: $(\$823.65 - \$0) \div (0.8941 - 0.81) = \$9,794$; PFMT vs pessary: $(\$823.65 - \$75) \div (0.8941 - 0.8580) = \$20,738$

^hSimpson et al⁸⁶ reported costs in US and Canadian dollars. We use Canadian dollars here because it is more relevant to Ontario.

ⁱWe calculated this value; it was not reported in the paper.

^jIn the PFMT group, 195 (95%) had stress urinary incontinence, 135 (66%) had urgency urinary incontinence, and 132 (64%) had both. In the control group, 195 (95%) had stress urinary incontinence, 156 (76%) had urgency urinary incontinence, and 151 (73%) had both.

^kSign change from “-0.002 (95% CI -0.027 to 0.023)”^{82,87} to be consistent with our minus sign use (i.e., a positive mean difference means favouring PFMT).

^lGlazener et al⁸⁸ used SF-6D instead of EQ-5D to measure health utilities in sensitivity analyses (SF-6D: adjusted mean difference 0.005 [95% CI -0.012 to 0.022] QALYs), which was still not statistically significant; however, it led to a lower ICER (£36,204 per QALY gained).

^mThe societal costs included the costs of time-off work and travel cost for the participant and a companion.

ⁿIn the PFMT group, 148 (67%) had stress urinary incontinence, 186 (85%) had urgency urinary incontinence, and 129 (59%) had both. In the control group, 136 (61%) had stress urinary incontinence, 183 (82%) had urgency urinary incontinence, and 112 (50%) had both.

^oGlazener et al⁸⁸ used SF-6D instead of EQ-5D to measure health utilities in sensitivity analyses (SF-6D: adjusted mean difference -0.004 [95% CI -0.020 to 0.012]), which was still not statistically significant.

^pBased on the description of cost components considered, the analysis was likely conducted from a health care system perspective.

^qPFMT: stage 1, n = 70; stage 2: n = 75; Control: stage 1, n = 85; stage 2: n = 57.

^rPanman et al^{82,87} used EQ-5D-3L to measure utility but did not report utility or total QALY values; no description was provided about how to estimate the QALY loss. The ICER estimate should be interpreted with caution because neither group nor incremental QALY values were reported.

^sPFMT: stage 1, n = 62; stage 2: n = 18; Control: stage 1, n = 58; stage 2: n = 24.

^tPanman et al⁸² also conducted a cost-effectiveness analysis using the Pelvic-Floor-Distress-Inventory as the effectiveness measure, but for simplicity, we did not include the findings in this review.

⁸²Panman et al⁸² stated that “Both treatment groups lost QALYs over the 2-year period, although loss of QALYs was slightly lower in the pessary group (0.024 in the pessary group and 0.065 in the PFMT group). This resulted in a negative ICUR [*incremental cost–utility ratio*] of $-\$27,439$ (95%CI, $-\$91,974$ to $\$74,695$), meaning an additional saving of $\$27,439$ per QALY lost.”⁸² This interpretation may not be accurate because the results show pessary led cost savings and with fewer QALYs lost. We interpreted the findings as PFMT was dominated by pessary because PFMT was associated with higher costs and more QALYs lost compared with pessary.

Applicability and Limitations of the Included Studies

Appendix 5 provides the results of the quality appraisal checklist for economic evaluations applied to the included studies. For women with stress urinary incontinence, both studies were partially applicable to the research question.^{85,86} Chang et al did not report the pathways after the failure of the initial treatment failure,⁸⁵ and Simpson et al included the device cost of pessary but not the physician fees.⁸⁶ Therefore, although both studies published showed consistent results and are highly relevant, they are considered partially applicable to the Ontario setting. For women with pelvic organ prolapse, we judged that both studies were partially applicable to the research question.^{82,87} For men with urinary incontinence after prostate surgery, both studies were partially applicable to the research question.⁸⁸

Discussion

We identified 6 studies that evaluated the cost-effectiveness of pelvic floor muscle training for stress urinary incontinence in women,^{85,86} pelvic organ prolapse in women,^{82,87} or urinary incontinence in men after prostate surgery.⁸⁸ We did not identify any economic studies evaluating pelvic floor muscle training for people with fecal incontinence. None of the included studies were directly applicable to the Ontario setting.

We excluded studies with surgical treatments as the only comparator. This is because study populations receiving surgical and nonsurgical treatments may differ (people indicated to receive surgical treatments may have more severe symptoms). A health technology assessment on vaginal pessaries conducted by Ontario Health in 2021³⁰ found that the pelvic floor muscle training as an initial treatment strategy was the most cost-effective for women with symptomatic stress urinary incontinence and pelvic organ prolapse (lower cost and higher QALY compared with other treatment strategies, although the difference in QALYs was very small). We excluded this economic analysis from our economic literature review as the comparator included surgeries and therefore did not meet our inclusion criteria.

For our review, we also focused on supervised pelvic floor muscle training programs, which typically comprise multiple 1-to-1 sessions with a health care professional qualified to guide patients in performing pelvic floor muscle training exercises. While unsupervised (or self-guided) pelvic floor muscle training (e.g., via mobile app or prerecorded video) may be available at a lower cost to patients, it may be also associated with higher uncertainty of effectiveness compared with supervised pelvic floor muscle training. In current practice, people with pelvic floor dysfunction may simultaneously be treated with pessaries and pelvic floor muscle training; however, we did not identify any economic studies that evaluated pessaries and pelvic floor muscle training as a combined treatment strategy.

Both studies involving women with urinary incontinence suggested the cost-effectiveness of pelvic floor muscle training (i.e., the treatment pathway initialing from pelvic floor muscle training) when compared with the alternative intervention (no treatment or pessary).^{85,86} These results were partially applicable to our research question; however, because a treatment pathway usually involves multiple treatments, it can be challenging to distinguish the contributions of initial and subsequent treatments.

According to our clinical evidence review, for women with pelvic organ prolapse, pelvic floor muscle training improved health outcomes when compared with no treatment; however, pelvic floor muscle training was associated with health care resource use (e.g., €254 in 2013 EUR for women with mild pelvic organ prolapse⁸⁷). Therefore, whether it was cost-effective or not was uncertain. Pelvic floor muscle training and pessary are likely associated with similar health outcomes, while pessary is

associated with lower costs; therefore, compared with pessary, pelvic floor muscle training is likely not cost-effective.

For men with urinary incontinence after prostate surgery, pelvic floor muscle training and control groups had very similar QALYs over a 1-year time horizon,⁸⁸ but pelvic floor muscle training group was associated with the costs of physical training. Therefore, in both trials reported by the paper,⁸⁸ the cost-effectiveness of pelvic floor muscle training was not established.

None of the economic evaluations explicitly addressed the impact of adherence on the effectiveness of pelvic floor muscle training. However, the health and economic impact of adherence to pelvic floor muscle training were reflected by the cost-effectiveness results (e.g., the standard deviations of the costs of pelvic floor muscle training programs) in 3 papers (4 trials).^{82,87,88}

Conclusions

Our systematic review of the economic literature identified 6 cost–utility analyses that evaluated the cost-effectiveness of pelvic floor muscle training in people with pelvic organ prolapse or urinary incontinence. For women with stress urinary incontinence, pelvic floor muscle training was likely cost-effective compared with other nonsurgical interventions. For women with pelvic organ prolapse, the cost-effectiveness of pelvic floor muscle training versus no active treatment was uncertain, and pelvic floor muscle training was likely not cost-effective compared with pessaries. Lastly, for men with urinary incontinence after prostate surgery, pelvic floor muscle training was likely not cost-effective compared with standard care without pelvic floor muscle training. We did not identify any economic studies on pelvic floor muscle training for women or men with fecal incontinence. None of the studies were conducted from the perspective of the Ontario Ministry of Health, and none of studies were directly applicable to the Ontario context.

Primary Economic Evaluation

We did not conduct a primary economic evaluation for pelvic floor muscle training, given the following considerations.

Stress Urinary Incontinence

Women

Our economic evidence review identified 2 studies that evaluated the cost-effectiveness of pelvic floor muscle training (1 in the US setting and 1 in the Canadian setting).^{85,86} Compared with no treatment, studies found pelvic floor muscle training to be either dominant (less costly and more effective)⁸⁵ or cost-effective (ICER \$9,794 CAD per QALY).⁸⁶ Both studies found that pelvic floor muscle training in comparison with pessaries was more costly and slightly more effective (ICER \$22,729 USD per QALY⁸⁵ and \$20,738 CAD per QALY⁸⁶).

We did not find any studies on the cost-effectiveness of pelvic floor muscle training plus pessaries compared with pessaries alone. In comparison with pessaries, pelvic floor muscle training plus pessaries resulted in little to no difference in symptoms or patient satisfaction (see Clinical Evidence Review). A health technology assessment on vaginal pessary (conducted by Ontario Health in 2021) also found that the “pelvic floor muscle training → Pessary → Surgery” treatment strategy was the most cost-effective for women with symptomatic stress urinary incontinence (lower cost and higher QALY when compared with the other treatment strategies, although the difference in QALYs was very small).³⁰ The findings were consistent with recommendations from the Canadian Urological Association and the Society of Obstetricians and Gynaecologists of Canada, namely, conservative first-line treatments for stress urinary incontinence should include supervised pelvic floor muscle training and vaginal pessaries.^{31,32}

For these reasons, we decided to forgo conducting a primary economic evaluation on pelvic floor muscle training for women. There were inadequate data to evaluate the cost-effectiveness of pelvic floor muscle training in different age groups, and it should be noted that the overall judgement of the cost-effectiveness of pelvic floor muscle training for the population with stress urinary incontinence may be not generalizable to specific population groups.

Men

For men, pelvic floor muscle training had little to no effect on symptoms, quality of life, and complications, and the evidence was very uncertain (see Clinical Evidence Review). In addition, in the paper that reported economic evaluations alongside 2 randomized controlled trials for this population, it was concluded that pelvic floor muscle training was unlikely to be cost-effective at commonly used willingness-to-pay values.^{82,87} Therefore, we did not conduct a primary economic evaluation for this population.

Fecal Incontinence

Adults

Pelvic floor muscle training was found to have little to no effect on symptoms, and the evidence was very uncertain (see Clinical Evidence Review); therefore, we did not conduct a primary economic

evaluation for this population. We also did not identify any published economic evaluations for this population.

Pelvic Organ Prolapse

Women

Our economic evidence review identified 2 trial-based economic evaluations assessing the cost-effectiveness of pelvic floor muscle training in the Netherlands.⁸²

The first study found that pelvic floor muscle training was more costly and less effective when compared with pessaries for women with symptomatic advanced prolapse. The study's probabilistic analysis found that 95% of the bootstrap replications showed pessary treatment was associated with greater effectiveness and lower cost than pelvic floor muscle training.⁸² Pelvic floor muscle training had little to no effect on symptoms compared with pessary treatment,⁸² and in the Netherlands, the cost of pelvic floor muscle training is higher than the cost of pessaries (which is also the case in Ontario).⁸⁷

The second study compared pelvic floor muscle training with no treatment, and found that it resulted in an ICER of €31,983 EUR per QALY (in 2013 euros) for mild prolapse over 2 years (approximately \$54,000 per QALY [in 2023 Canadian dollars]) and the cost-effectiveness of pelvic floor muscle training was highly uncertain (in probabilistic analysis, 45% of the simulations showed that pelvic floor muscle training was more costly and less effective).⁸⁷ Although our Clinical Evidence Review found that pelvic floor muscle training likely improves symptoms, quality of life, and patient satisfaction in women with pelvic organ prolapse, we consider the findings of the Netherlands study likely reasonable. In addition, we did not identify any long-term effectiveness data of pelvic floor muscle training or better utility data. Lastly, pelvic floor muscle training is individualized based on patient's specific needs and this may be associated with large variations in clinical effectiveness in practice. The large variations may lead to uncertain results in the economic model. Therefore, an Ontario-focused primary economic evaluation would likely have similar results, limitations, and uncertainties. For these reasons, we decided to forgo conducting a primary economic evaluation for this population.

Ontario Health also found that the “pelvic floor muscle training → Pessary → Surgery” treatment strategy was the most cost-effective for women with symptomatic pelvic organ prolapse (lower cost and higher QALY in comparison with other treatment strategies, although the difference in QALYs was very small).³⁰ The findings are consistent with recommendations in guidelines from the Canadian Urological Association and the Society of Obstetricians and Gynaecologists of Canada; conservative first-line treatments for pelvic organ prolapse should include supervised pelvic floor muscle training and vaginal pessaries.³²

Men

No clinical or economic studies that examined the use of pelvic floor muscle training in men with pelvic organ prolapse (e.g., rectal prolapse) were identified.

Budget Impact Analysis

Research Question

What is the potential 5-year budget impact for the Ontario Ministry of Health of publicly funding pelvic floor muscle training for adults with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse?

Methods

Analytic Framework

We estimated the budget impact of publicly funding pelvic floor muscle training using the cost difference between 2 scenarios: (1) current clinical practice without public funding of pelvic floor muscle training for adults with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse (the current scenario), and (2) anticipated clinical practice with public funding of pelvic floor muscle training for these populations (the new scenario). Figure 3 presents the model schematic.

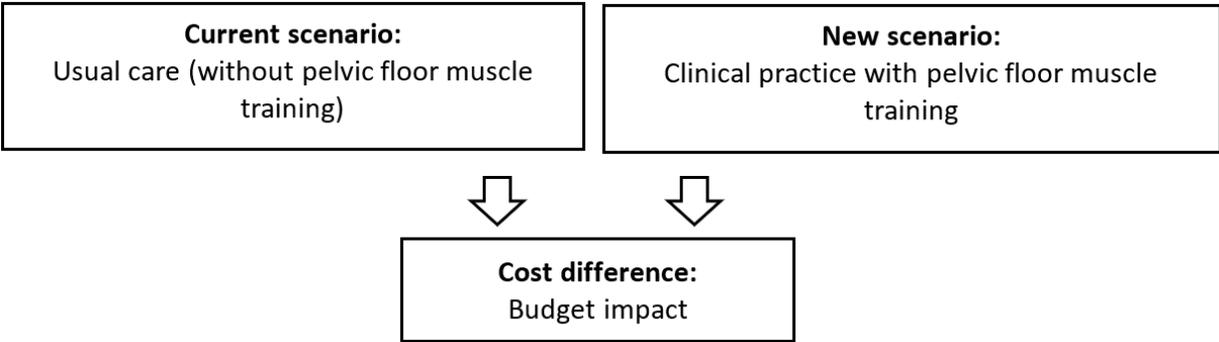


Figure 3: Schematic Model of Budget Impact

Flow chart describing the model for the budget impact analysis. The current scenario would explore resource use and total costs without public funding for pelvic floor muscle training. The new scenario would explore resource use and total costs *with* public funding for pelvic floor muscle training. The budget impact would represent the difference in costs between the 2 scenarios.

Key Assumptions

- One individual can receive up to 1 pelvic floor muscle training program each year
- The use of pelvic floor muscle training does not impact other health care costs related to the management of pelvic floor dysfunction and will not significantly impact the overall prevalence of pelvic floor dysfunction over the next 5 years

Population of Interest

Our clinical population of interest was women and men with moderate or severe stress urinary incontinence (a subtype of urinary incontinence), fecal incontinence, or pelvic organ prolapse. For this

budget impact analysis, we specified moderate or severe symptoms of pelvic floor dysfunctions that are likely to impact their routine life.

Prevalence of Pelvic Floor Dysfunction

The prevalence rates of urinary incontinence, fecal incontinence, and pelvic organ prolapse ranged widely in the literature.⁸⁹⁻⁹³ This may be attributed to heterogeneity in the populations investigated, methods used to identify pelvic floor dysfunction (e.g., self-reported versus medical examination) and how conditions are defined (for urinary incontinence, e.g., any urinary leakage in past 1 month versus any urinary leakage in the past 12 months).

Since age and sex are key factors that impact the prevalence of pelvic floor dysfunction, we aimed to identify sex- and age-specific prevalence when possible. Because we could not find Canadian prevalence data for pelvic floor dysfunction, we used published (US National Health and Nutritional Examination Survey [NHANES] in 2005–2006, 2007–2008, and 2009–2010) prevalence data: for women from 7,924 nonpregnant women ≥ 20 years old from 2005–2006, 2007–2008, and 2009–2010⁹⁴; for men with urinary incontinence, from a total of 5,297 adults (≥ 20 years old) from 2005–2006 and 2007–2008⁹⁵; and for men with fecal incontinence, from a total of 7,248 adults (≥ 20 years old) from 2005–2006, 2007–2008, and 2009–2010.⁸ The prevalence rates of pelvic floor dysfunction did not change from 2005 to 2010.

These prevalence data represent symptomatic pelvic floor dysfunction (self-reported to have had a negative impact on individuals' routine life) based on the following definitions:

- Urinary incontinence: 3 or higher on a urinary incontinence severity index (range of possible scores: 0–12), which includes questions about the frequency of episodes and the amount of leakage
- Fecal incontinence: leakage of mucus, liquid, or solid stool occurring at least monthly⁹⁴ (or at least once in the preceding month⁸)
- Pelvic organ prolapse: seeing or feeling a bulge (reported by respondents)
- ≥ 1 pelvic floor disorder: meeting at least 1 of the criteria listed above

To estimate stress urinary incontinence prevalence for women, we used data for stress urinary incontinence from a study⁹⁶ based on NHANES 2015–2018; people with stress urinary incontinence were defined as those who responded “Yes” to the question: “During the past 12 months, have you leaked or lost control of even a small amount of urine with an activity like coughing, lifting or exercise?” For men, we used data from a study⁹⁵ based on NHANES 2005–2006 and 2007–2008. We assumed that proportions (Table 25) were applicable to all age groups.

Table 25: Types of Urinary Incontinence

Subtype of urinary incontinence	Percentage distribution (%)	References
Women		
Stress urinary incontinence	37.5	US survey ⁹⁶
Urgency urinary incontinence	22.0	US survey ⁹⁶
Mixed urinary incontinence ^a	31.3	US survey ⁹⁶
Unspecified urinary incontinence	9.2	US survey ⁹⁶
Men		
Stress urinary incontinence	12.5	US survey ⁹⁵
Urge urinary incontinence	48.6	US survey ⁹⁵
Mixed urinary incontinence ^b	15.4	US survey ⁹⁵
Other urinary incontinence	23.5	US survey ⁹⁵

Abbreviation: US, United States.

^aPeople with both stress urinary incontinence and urgency urinary incontinence.

Estimated Size of Population With Pelvic Floor Disorders in Ontario

We multiplied Ontario population data (Table A21) in 2022⁹⁷ with the corresponding sex- and age-specific US prevalence rate (Table A19 and Table A20) to yield estimates for the number of people with pelvic floor dysfunction in Ontario by sex and by age (Table A22 and Table A23); for stress urinary incontinence, the proportion (for women, 37.5%⁹⁶; for men, 12.5%⁹⁵) of stress urinary incontinence to urinary incontinence was multiplied by the prevalence rate of urinary incontinence for each age group.

We regrouped population data into 3 age groups for women (18 to 44, 45 to 64, and ≥ 65 years) and 2 age groups for men (18 to 64 years and ≥ 65 years) for the budget impact analysis (Table A24). Based on the trend in adult population from 2018 to 2022 (Table A21), we assumed that the figure for each group with pelvic floor dysfunction would increase by 1.5% annually to yield projected clinical population sizes for women and men with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse from 2024 to 2028 (Table 26).

Table 26: Projected Estimates for Adults in Ontario With Pelvic Floor Dysfunction

	Year 1 (2024)	Year 2 (2025)	Year 3 (2026)	Year 4 (2027)	Year 5 (2028)
Stress urinary incontinence					
Women, n	424,444	430,811	437,273	443,832	450,489
18 to 44 years, n	82,389	83,625	84,879	86,152	87,444
45 to 64 years, n	163,551	166,004	168,494	171,021	173,586
≥ 65 years, n	178,504	181,182	183,900	186,659	189,459
Men, n	39,235	39,824	40,421	41,027	41,642
18 to 64 years, n	17,816	18,083	18,354	18,629	18,908
≥ 65 years, n	21,419	21,740	22,066	22,397	22,733
Fecal incontinence					
Women, n	629,424	638,865	648,448	658,175	668,048
18 to 44 years, n	123,725	125,581	127,465	129,377	131,318
45 to 64 years, n	244,245	247,909	251,628	255,402	259,233
≥ 65 years, n	261,454	265,376	269,357	273,397	277,498
Men, n	474,385	481,501	488,724	496,055	503,496
18 to 64 years, n	301,329	305,849	310,437	315,094	319,820
≥ 65 years, n	173,055	175,651	178,286	180,960	183,674
Pelvic organ prolapse					
Women, n	189,887	192,735	195,626	198,560	201,538
18 to 44 years, n	40,764	41,375	41,996	42,626	43,265
45 to 64 years, n	79,671	80,866	82,079	83,310	84,560
≥ 65 years, n	69,451	70,493	71,550	72,623	73,712
Men, n					
18 to 64 years, n	—	—	—	—	—
≥ 65 years, n	—	—	—	—	—

In the present budget impact analysis, our population of interest are those who are presently affected by these conditions. Thus, the prevalence rates reflect the objectives of our analyses. This is because, if we broaden our population to include those with historical or minor pelvic floor dysfunction symptoms, the size of our population would be substantially larger.

Current Intervention Mix

Some treatment options for pelvic floor dysfunction (such as behavioural modification and dietary adjustments, which is mainly for fecal incontinence¹⁴) do not directly impact public health care system funding from the Ministry of Health perspective. People over 65 years old, or recipients of Ontario Works or the Ontario Disability Support Program, receive publicly funded prescription drug coverage (e.g., for medications for fecal incontinence).⁹⁸

Pelvic floor muscle training and vaginal pessaries are not currently publicly funded (at the time of analysis).

Pelvic floor muscle training is primarily provided by physiotherapists with specialized training. Physicians, registered nurses, and midwives can also provide pelvic floor muscle training after specialized training. But presently, few health care professionals have been trained to provide pelvic floor muscle training in the public health care system (Sinéad Dufour, email communication, November 2023). For simplicity, we assumed that currently very few patients receive publicly funded pelvic floor muscle training.

Uptake of the New Intervention

The uptake rate of pelvic floor muscle training for each pelvic floor disorder was estimated by age group for both men and women. The uptake rate of a pelvic floor disorder for a given sex and age-group is the number of people with pelvic floor dysfunction receiving pelvic floor muscle training divided by the total number of people with pelvic floor dysfunction within a given sex and age group (and can be expressed as a percentage by multiplying by 100). We estimated the uptake rates of pelvic floor muscle training in the new scenario (Table 27) based on consultations with stakeholders and the following considerations:

- The uptake of pelvic floor muscle training will likely be small initially because, presently, there is an inadequate number of health care professionals qualified to provide pelvic floor muscle training in the public health care system. See Background.
- With more patient education, we expect that more people will become aware of pelvic floor muscle training (see Patient Preferences and Values); more health care professionals will train and be able to offer pelvic floor muscle training services; therefore, uptake rates will likely increase yearly
- Pelvic floor muscle training may be used alone, or jointly with other interventions, so people who have received other treatments may also receive pelvic floor muscle training
- For some people with pelvic floor dysfunction, pelvic floor muscle training may not be suitable
- We assumed that most people may not need more pelvic floor muscle training over the subsequent few years after completing 1 course of pelvic floor muscle training treatment
- Our estimated uptake of this intervention reflects the proportion of people who receive pelvic floor muscle training with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse as the primary indication. However, some people may receive physiotherapy to treat a primary concern other than pelvic floor dysfunction (e.g., for poststroke rehabilitation). During these physiotherapy sessions, pelvic floor muscle training may be provided to address a secondary concern (e.g., stress urinary incontinence). Our estimated uptake rate does not take into account pelvic floor muscle training services undertaken to address pelvic floor dysfunction as a secondary concern

Table 27: PFMT Uptake Rates in New Scenario, by Condition and Sex

	Year 1	Year 2	Year 3	Year 4	Year 5
Stress urinary incontinence uptake rate					
Women					
18 to 44 years, %	10	12	14	16	18
45 to 64 years, %	10	12	14	16	18
≥ 65 years, %	5	6	7	8	9
Men					
18 to 64 years, %	5	6	7	8	9
≥ 65 years, %	5	6	7	8	9
Fecal incontinence uptake rate					
Women					
18 to 44 years, %	10	12	14	16	18
45 to 64 years, %	10	12	14	16	18
≥ 65 years, %	5	6	7	8	9
Men					
18 to 64 years, %	5	6	7	8	9
≥ 65 years, %	5	6	7	8	9
Pelvic organ prolapse uptake rate					
Women					
18 to 44 years, %	10	12	14	16	18
45 to 64 years, %	10	12	14	16	18
≥ 65 years, %	5	6	7	8	9
Men					
18 to 64 years, %	—	—	—	—	—
≥ 65 years, %	—	—	—	—	—

Table 28: Patient Volume Estimates for PFMT in New Scenario, by Condition and Sex

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Stress urinary incontinence volume						
Women, n	33,519	40,826	48,345	56,080	64,036	242,806
18 to 44 years, n	8,239	10,035	11,883	13,784	15,740	59,681
45 to 64 years, n	16,355	19,920	23,589	27,363	31,245	118,472
≥ 65 years, n	8,925	10,871	12,873	14,933	17,051	64,653
Men, n	1,962	2,389	2,830	3,282	3,748	14,211
18 to 64 years, n	891	1,085	1,285	1,490	1,702	6,453
≥ 65 years, n	1,071	1,304	1,545	1,792	2,046	7,758
Fecal incontinence volume						
Women, n	49,871	60,742	71,928	83,436	95,274	361,251
18 to 44 years, n	12,373	15,070	17,845	20,700	23,637	89,625
45 to 64 years, n	24,425	29,749	35,228	40,864	46,662	176,928
≥ 65 years, n	13,073	15,923	18,855	21,872	24,975	94,698
Men, n	23,719	28,890	34,211	39,685	45,315	171,820
18 to 64 years, n	15,066	18,351	21,731	25,208	28,784	109,140
≥ 65 years, n	8,653	10,539	12,480	14,477	16,531	62,680
Pelvic organ prolapse volume						
Women, n	15,516	18,899	22,379	25,960	29,643	112,397
18 to 44 years, n	4,076	4,965	5,879	6,820	7,788	29,528
45 to 64 years, n	7,967	9,704	11,491	13,330	15,221	57,713
≥ 65 years, n	3,473	4,230	5,009	5,810	6,634	25,156
Men, n	—	—	—	—	—	—
18 to 64 years, n	—	—	—	—	—	—
≥ 65 years, n	—	—	—	—	—	—

Resources and Costs

We reviewed published literature and consulted stakeholders to estimate the average costs of pelvic floor muscle training. The cost of pelvic floor muscle training therapy is directly linked to the overall number of health care professional hours required (i.e., the number of pelvic floor muscle training sessions and the duration of training sessions). Published studies reported that the total number of pelvic floor muscle training sessions varied from 4 sessions⁸⁸ to greater than 20 sessions.^{34,84} Clinical guidelines³¹ currently do not include guidance on the specific number of pelvic floor muscle training sessions that patients should receive, because it should be determined on an individual basis, but we took INESSS data and recommendations regarding minimum and maximum number of sessions into consideration – a maximum of 10 sessions was recommended for the treatment of urinary incontinence⁴² and pelvic organ prolapse⁴² in women, and a minimum of 5 and maximum of 10 sessions was used in their budget impact analysis when modelling urinary incontinence treatment for adult women.⁹⁹

Considerations

Unit

- We estimated the average cost of pelvic floor muscle training per person not per training session. Currently, clinic-based physiotherapy in Ontario is based on an episode of care model not individual visits.¹⁰⁰

Clinician-to-Patient Ratio

- We considered individual-based pelvic floor muscle training (1 therapist for 1 patient). Although group-based pelvic floor muscle training can be conducted and was less costly compared with individual-based pelvic floor muscle training,¹⁰¹ it is challenging to implement in practice (i.e., finding sufficient patients who need and can attend training sessions at the same time [Kate Jones, email communication, 2023 August]). Currently, health care professionals generally provide 1-to-1 pelvic floor muscle training in Ontario, although group-based pelvic floor muscle training is also sometimes offered (Sinéad Dufour, email communication, 2023 August; Kate Jones, email communication, 2023 August).

Treatment Components

- We focused solely on pelvic floor muscle training and did not include adjunct components (e.g., biofeedback).

Number of Sessions and Session Duration

- We did not differentiate pelvic floor muscle training costs by condition.
- Most clinical and economic data^{41,42,99,101} were based on studies with women. For simplicity, we do not differentiate costs by sex.
- We assumed that most individuals would participate in 5 to 8 sessions (Kate Jones, email communication, 2023 August; Nelly Faghani, verbal communication, 2023 March). (Note it is expected that some patients may not complete all sessions in prescribed program; the range stated here represents sessions received)
- We estimated the actual cost (not prices charged) of pelvic floor muscle training based on those from the provider perspective in a Canadian study¹⁰¹
 - The pelvic floor muscle training program, which began with assessment and education, followed by 10 to 12 weekly visits (1 hour per session), had a mean cost of \$954 (after adjustment to 2023 Canadian dollars using the Canadian consumer price index¹⁰²).
 - The provider perspective of the pelvic floor muscle training cost reflected the labour market salary for specialized physiotherapists, treatment room, staff time, consumables, and all equipment necessary for pelvic floor muscle training.
- We took into consideration that the average labour salary level and the cost of treatment rooms in Ontario are slightly higher than those in Quebec.^{102,103}

Cost

Since the number of pelvic floor muscle training sessions is expected to be lower than those reported (e.g., 5–8 sessions rather than 10–12 sessions¹⁰¹), the mean cost of pelvic floor muscle training program was estimated to be \$763, which is 80% of the pelvic floor muscle training mean cost reported by Cacciari et al.⁸⁶

This estimate is consistent with the rate of charge for pelvic floor muscle training in private physiotherapy clinics in Ontario (e.g., \$150 for a 60-minute session, and \$100 for a 30-minute session),¹⁰⁴ costs reported by INESSS (\$105 per session in 2020),⁴² and costs reported in another paper based on Canadian data (4–6 sessions: \$715 [SD \$142.50] in 2017 Canadian dollars).⁸⁶

Internal Validation

The secondary health economist conducted formal internal validation. This process included checking for errors and ensuring the accuracy of parameter inputs and equations in the budget impact analysis.

Analysis

We conducted a reference case analysis and sensitivity analyses. Our reference case analysis represents the analysis with the most likely set of input parameters and model assumptions. Our sensitivity analyses explored how the results are affected by varying input parameters and model assumptions; we used the same parameters as in the reference case analysis, with the exception of those specified below for each analysis.

Scenarios

- *Change in patient volume estimate for men with stress urinary incontinence, with new estimate based on Ontario radical prostatectomy data*
 - Only post–radical prostatectomy stress urinary incontinence was included because most clinical evidence for pelvic floor muscle training for men with stress urinary incontinence is based on this population.
 - Post–radical prostatectomy urinary incontinence is common; it was estimated that about 8% to 25% people who undergo radical prostatectomy experience urinary incontinence.¹⁰⁵
 - We identified the annual number of radical prostatectomy procedures conducted in Ontario (including open, robotic, or laparoscopic) using Canadian Institute for Health Information Discharge Abstract Database inpatient data from fiscal years 2017 to 2021 (IntelliHealth Ontario, intellihealth.moh.gov.on.ca; December 2023). Yearly volume was relatively consistent, and a mean of 1,862 radical prostatectomies were conducted annually.
 - We assumed that 300 individuals (about 16%) would experience post–radical prostatectomy urinary incontinence, and would be eligible for PFMT treatment.
 - Given the small population size, we assumed that the uptake would be 60% in year 1 and increase by 5 percentage points annually to 80% in year 5 (Table 29).

- *Change in volume estimate, by taking into consideration individuals with more than 1 type of pelvic floor dysfunction*
 - Individuals may have more than 1 type of pelvic floor dysfunction (Table A24). This scenario counts an individual only once if they have more than 1 condition (urinary incontinence, fecal incontinence and pelvic organ prolapse). Note that this scenario included all types of urinary incontinence, not only stress urinary incontinence.
 - We assumed that the uptake rates would be the same as those for women and men with stress urinary incontinence to yield the new projected estimates (Table 29).
- *Higher uptake due to the availability of virtual pelvic floor muscle training*
 - Widespread availability of virtual pelvic floor muscle training may improve uptake rates, by improving access for people who live in remote areas or who have challenges with their mobility.
 - Currently, virtual pelvic floor muscle training is often provided in private clinics, and experts are of the opinion that it will be feasible to deliver in the publicly funded health care system, because numerous clinics have offered virtual care since the COVID-19 pandemic (Sinéad Dufour, written communication, 2023 December; Kate Jones, written communication, 2023 December; Nelly Faghani, written communication, 2023 December), and clinical practice guidelines for urinary incontinence indicated that virtual care is effective for all urogynecology care.⁴⁵ However, it may be preferred that patients visit clinics in person at least once so therapists can conduct a pelvic exam to understand the patients' conditions, and prepare the individualized pelvic floor muscle training plans.
 - In general, the cost of a virtual session (delivered by physiotherapists) is the same as that of an in-person session, because the cost of pelvic floor muscle training is largely driven by therapist time required (Sinéad Dufour, written communication, 2023 December; Kate Jones, written communication, 2023 December; Nelly Faghani, written communication, 2023 December).
 - We assumed that uptake rates would be 25% higher than those in the reference case analysis, yielding higher patient volume estimates (Table 29).
- *Lower patient volume estimate due to treatment with pessaries being funded publicly*
 - Patient volume estimates for pelvic floor muscle training may be lower than those in the reference case analysis, because patients being treated with pessaries may not make use of pelvic floor muscle training.
 - Publicly funding pessaries may have limited impact on the budget impact of pelvic floor muscle training in initial years.
 - Presently, treatment with a pessary is often used for women with stress urinary incontinence or pelvic organ prolapse, and although the physician fee for pessary fitting is publicly funded in Ontario,³⁰ pessary devices are not publicly funded (i.e., out of pocket or through private insurance; device cost: \$75 CAD in 2017; the pessary device can be used for several years⁸⁶). Also, it is possible that individuals with a pessary also receive pelvic floor muscle training.

- In the long term, when considering both incidence and pessary replacements, the impact may be greater.
- o We assumed that patient volumes for pelvic floor muscle training would be 10%, 12%, 14%, 17% and 20% lower than those in year 1, 2, 3, 4, and 5, respectively, for women with stress urinary incontinence and pelvic organ prolapse in the reference case (Table 29).

Table 29: Parameter Changes for Scenario Analyses

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Change in patient volume estimate for men with stress urinary incontinence, with new estimate based on radical prostatectomy data						
Reference case						
Men, stress urinary incontinence	1,962	2,389	2,830	3,282	3,748	14,211
Scenario analysis						
Men, stress urinary incontinence	180	195	210	225	240	1,050
Change in volume estimate, by taking into consideration individuals may have ≥ 1 pelvic floor disorder						
Reference case						
	NA	NA	NA	NA	NA	NA
Scenario analysis						
Women	132,440	161,312	191,020	221,583	253,020	959,375
Men	35,387	43,101	51,038	59,205	67,604	256,335
Change in patient volume estimate, because of 25% higher uptake (if virtual pelvic floor muscle training is offered)						
Reference case						
Women						
Stress urinary incontinence	33,519	40,826	48,345	56,080	64,036	242,806
Fecal incontinence	49,871	60,742	71,928	83,436	95,274	361,251
Pelvic organ prolapse	15,516	18,899	22,379	25,960	29,643	112,397
Men						
Stress urinary incontinence	1,962	2,389	2,830	3,282	3,748	14,211
Fecal incontinence	23,719	28,890	34,211	39,685	45,315	171,820
Pelvic organ prolapse	—	—	—	—	—	—
Scenario analysis						
Women						
Stress urinary incontinence	41,899	51,033	60,431	70,100	80,045	303,508
Fecal incontinence	62,339	75,928	89,910	104,295	119,093	451,565
Pelvic organ prolapse	19,395	23,624	27,974	32,450	37,054	140,497
Men						
Stress urinary incontinence	2,453	2,986	3,538	4,103	4,685	17,765
Fecal incontinence	29,649	36,113	42,764	49,606	56,644	214,776
Pelvic organ prolapse	—	—	—	—	—	—
Change in patient volume estimate, because of lower uptake (due to treatment with pessary being funded publicly)						
Reference case						
Women, stress urinary incontinence	33,519	40,826	48,345	56,080	64,036	242,806
Women, pelvic organ prolapse	15,516	18,899	22,379	25,960	29,643	112,397
Scenario analysis						
Women, stress urinary incontinence	30,167	35,927	41,577	46,546	51,229	205,446
Women, pelvic organ prolapse	13,964	16,631	19,246	21,547	23,714	95,102

We also conducted the following sensitivity analyses:

- *Higher pelvic floor muscle training costs (20% higher than the reference case)*
 - For various reasons, the costs of pelvic floor muscle training can be higher (e.g., more sessions, higher adherence rate, adjunct components included, or physician as health care professional).
- *Lower pelvic floor muscle training costs (20% lower than the reference case)*
 - For various reasons, the average costs of pelvic floor muscle training can be lower (e.g., group-based training, lower adherence)
 - For example, the group-based physiotherapy may be performed in some physiotherapy clinics located in the high population density areas, the increased volumes may mainly lead the increase of the workload and associated salary of professionals and staff, while the costs of treatment room and overhead costs do not change, so the average costs may become lower with the increase of volumes of pelvic floor muscle training. In addition, the feasibility of using app-based pelvic floor muscle training may reduce the number of supervised follow-up visits. Lastly, the actual adherence of patients to all prescribed sessions of pelvic floor muscle training may be lower than what is assumed in our reference case.
- *Greater volume of pelvic floor muscle training (40% higher than the reference case analysis)*
 - Larger clinical population (e.g., using broader definitions for population of interest) or higher uptake rate
- *Smaller volume of pelvic floor muscle training (40% lower than the reference)*
 - Smaller clinical population or the lower uptake rate

Results

Reference Case

Results of the budget impact analysis for women and men are shown in Table 30. The total cost of pelvic floor muscle training in the current scenario was assumed to be zero, given that pelvic floor muscle training is not publicly funded. Publicly funding pelvic floor muscle training would result in total additional costs over 5 years of \$185.3 million, \$275.6 million, and \$85.8 million for women with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse, respectively; publicly funding pelvic floor muscle training would result in total additional costs over 5 years of \$10.8 million and \$131.1 million for men with stress urinary incontinence and fecal incontinence, respectively.

Table 30: Budget Impact Analysis Results (Reference Case), by Condition and Sex

	Budget impact, \$ million ^{a,b}					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Stress urinary incontinence						
Women						
Current scenario	0	0	0	0	0	0
New scenario	25.6	31.2	36.9	42.8	48.9	185.3
Budget impact	25.6	31.2	36.9	42.8	48.9	185.3
Men						
Current scenario	0	0	0	0	0	0
New scenario	1.5	1.8	2.2	2.5	2.9	10.8
Budget impact	1.5	1.8	2.2	2.5	2.9	10.8
Fecal incontinence						
Women						
Current scenario	0	0	0	0	0	0
New scenario	38.1	46.3	54.9	63.7	72.7	275.6
Budget impact	38.1	46.3	54.9	63.7	72.7	275.6
Men						
Current scenario	0	0	0	0	0	0
New scenario	18.1	22	26.1	30.3	34.6	131.1
Budget impact	18.1	22	26.1	30.3	34.6	131.1
Pelvic organ prolapse						
Women						
Current scenario	0	0	0	0	0	0
New scenario	11.8	14.4	17.1	19.8	22.6	85.8
Budget impact	11.8	14.4	17.1	19.8	22.6	85.8
Men						
Current scenario	0	0	0	0	0	0
New scenario	—	—	—	—	—	—
Budget impact	—	—	—	—	—	—

^aIn 2023 Canadian dollars.

^bResults may appear inexact due to rounding.

Sensitivity Analysis

The potential budget impact of publicly funding pelvic floor muscle training for men with postprostatectomy urinary incontinence was small (Table 31). The total additional budget of funding pelvic floor muscle training for adults, when adjusting patient volume estimates for overlap between clinical populations (i.e., taking into consideration that some may have more than 1 type of pelvic floor dysfunction) would be approximately \$927.6 million (\$732.0 million and \$195.6 million for women and men, respectively). If the virtual pelvic floor muscle training is widely available, the budget impact would be greater than that in the reference case, and if treatment with a pessary is publicly funded, the budget impact of pelvic floor muscle training may be slightly lower than that in the reference case.

Table 31: Budget Impact Analysis Results (Scenario Analyses)

Scenario	Budget impact, \$ million ^{a,b}					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Change in patient volume estimate for men with stress urinary incontinence, with new estimate based on radical prostatectomy data						
Reference case						
Men, stress urinary incontinence	1.5	1.8	2.2	2.5	2.9	10.8
Scenario analysis						
Men, stress urinary incontinence	0.14	0.15	0.16	0.17	0.18	0.80
Change in volume estimate, by taking into consideration individuals may have ≥ 1 pelvic floor disorder						
Reference case						
	NA					
Scenario analysis						
Women	101.1	123.1	145.7	169.1	193.1	732.0
Men	27.0	32.9	38.9	45.2	51.6	195.6
Change in patient volume estimate because of 25% higher uptake (if virtual pelvic floor muscle training is offered)						
Reference case						
Women						
Stress urinary incontinence	25.6	31.2	36.9	42.8	48.9	185.3
Fecal incontinence	38.1	46.3	54.9	63.7	72.7	275.6
Pelvic organ prolapse	11.8	14.4	17.1	19.8	22.6	85.8
Men						
Stress urinary incontinence	1.5	1.8	2.2	2.5	2.9	10.8
Fecal incontinence	18.1	22	26.1	30.3	34.6	131.1
Pelvic organ prolapse	—	—	—	—	—	—
Scenario analysis						
Women						
Stress urinary incontinence	32.0	38.9	46.1	53.5	61.1	231.6
Fecal incontinence	47.6	57.9	68.6	79.6	90.9	344.6
Pelvic organ prolapse	14.8	18.0	21.3	24.8	28.3	107.2
Men						
Stress urinary incontinence	1.9	2.3	2.7	3.1	3.6	13.6
Fecal incontinence	22.6	27.6	32.6	37.8	43.2	163.8
Pelvic organ prolapse	—	—	—	—	—	—
Change in patient volume estimate because of lower uptake due to treatment with a pessary being funded publicly						
Reference case						
Women, stress urinary incontinence	25.6	31.2	36.9	42.8	48.9	185.3
Women, pelvic organ prolapse	11.8	14.4	17.1	19.8	22.6	85.8
Scenario analysis						
Women, stress urinary incontinence	23.0	27.4	31.7	35.5	39.1	156.7
Women, pelvic organ prolapse	10.7	12.7	14.7	16.4	18.1	72.6

Abbreviations: FI, fecal incontinence; POP, pelvic organ prolapse; SUI, stress urinary incontinence; UI, urinary incontinence.

^aIn 2023 Canadian dollars.

^bResults may appear inexact due to rounding.

The potential budget impact result was sensitive to change in average pelvic floor muscle training program cost and change patient volume (Table 32).

Table 32: Budget Impact Analysis Results (Sensitivity Analyses)

Scenario	Budget impact, \$ million ^a					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total ^b
Reference case						
Women						
Stress urinary incontinence	25.6	31.2	36.9	42.8	48.9	185.3
Fecal incontinence	38.1	46.3	54.9	63.7	72.7	275.6
Pelvic organ prolapse	11.8	14.4	17.1	19.8	22.6	85.8
Men						
Stress urinary incontinence	1.5	1.8	2.2	2.5	2.9	10.8
Fecal incontinence	18.1	22	26.1	30.3	34.6	131.1
Pelvic organ prolapse	—	—	—	—	—	—
Higher PFMT costs, 20% higher than the reference case						
Women						
Stress urinary incontinence	30.7	37.4	44.3	51.4	58.7	222.5
Fecal incontinence	45.7	55.6	65.9	76.4	87.2	330.8
Pelvic organ prolapse	14.2	17.3	20.5	23.8	27.1	102.9
Men						
Stress urinary incontinence	1.8	2.2	2.6	3.0	3.5	13.1
Fecal incontinence	21.7	26.4	31.3	36.4	41.5	157.3
Pelvic organ prolapse	—	—	—	—	—	—
Lower PFMT costs, 20% lower than the reference case						
Women						
Stress urinary incontinence	20.5	25.0	29.5	34.2	39.1	148.3
Fecal incontinence	30.5	37.0	43.9	51.0	58.2	220.6
Pelvic organ prolapse	9.4	11.5	13.7	15.8	18.1	68.5
Men						
Stress urinary incontinence	1.2	1.4	1.8	2	2.3	8.7
Fecal incontinence	14.5	17.6	20.9	24.2	27.7	104.9
Pelvic organ prolapse	—	—	—	—	—	—
Greater volume of PFMT, 40% higher than the reference						
Women						
Stress urinary incontinence	35.8	43.7	51.7	59.9	68.5	259.6
Fecal incontinence	53.3	64.8	76.9	89.2	101.8	386.0
Pelvic organ prolapse	16.5	20.2	23.9	27.7	31.6	119.9
Men						
Stress urinary incontinence	2.1	2.5	3.1	3.5	4.1	15.3
Fecal incontinence	25.3	30.8	36.5	42.4	48.4	183.4
Pelvic organ prolapse	—	—	—	—	—	—

Scenario	Budget impact, \$ million ^a					
	Year 1	Year 2	Year 3	Year 4	Year 5	Total ^b
Smaller volume of PFMT, 40% lower than the reference						
Women						
Stress urinary incontinence	15.4	18.7	22.1	25.7	29.3	111.2
Fecal incontinence	22.9	27.8	32.9	38.2	43.6	165.4
Pelvic organ prolapse	7.1	8.6	10.3	11.9	13.6	51.5
Men						
Stress urinary incontinence	0.9	1.1	1.3	1.5	1.7	6.5
Fecal incontinence	10.9	13.2	15.7	18.2	20.8	78.8
Pelvic organ prolapse	—	—	—	—	—	—

Abbreviations: PFMT, pelvic floor muscle training.

^a In 2023 Canadian dollars.

^b Results may appear inexact due to rounding.

Discussion

We estimated the costs associated with pelvic floor muscle training but did not include any potential downstream cost savings associated with pelvic floor muscle training due to uncertainty in the clinical evidence. Our Clinical Evidence Review showed that pelvic floor muscle training likely improves symptoms for women with stress urinary incontinence and pelvic organ prolapse, in comparison with no treatment or usual care. Therefore, pelvic floor muscle training may reduce the uses of other health care resources associated with these symptoms and products for urinary incontinence for the publicly funded health care system and individual families, respectively; however, the magnitude of potential savings from pelvic floor muscle training is difficult to quantify because of a lack of data to address this issue. In addition, although we consulted several stakeholders, a lot of uncertainty remained regarding potential uptake rates.

Pelvic floor muscle training may also include adjunct treatments, such as biofeedback, electrical stimulation, and vaginal cones, but these are not recommended for women with urinary incontinence in the guidelines due to lacking of evidence of its benefits over the basic pelvic floor muscle training.³¹ Commonly pelvic floor muscle training is classified as a physical therapy, but pelvic floor muscle training includes both physical or behavioral components.³⁷ If pelvic floor muscle training is publicly funded, a large number of trained professionals will be needed to offer pelvic floor muscle training for the Ontario population.

It is not straightforward to understand how pelvic floor muscle training will be implemented or the actual budget impact for Ontario if pelvic floor muscle training is publicly funded in the future. In the present analysis, we used a model of care with associated cost that resembles what is currently used in private practice for physiotherapists. We acknowledge that an implementation model for pelvic floor muscle training may result in different costs for pelvic floor muscle training programs and a different budget impact.

Equity Considerations

We included a scenario analysis of the availability of virtual pelvic floor muscle training, which is especially feasible for people living in remote areas and these with challenges in mobility.

Strengths and Limitations

Our study had the following strengths:

- We consulted several stakeholders to understand current funding and the context of pelvic floor muscle training in Ontario
- Our key parameters and main assumptions were verified by clinical experts in Ontario

The following limitations should be noted when interpreting the findings of this analysis:

- We did not consider any potential cost savings associated with pelvic floor muscle training due to uncertainty in the clinical evidence
- Predicting the potential uptake rates and volume of pelvic floor muscle training after pelvic floor muscle training is publicly funded is not straightforward. Although we made efforts to provide the reasonable estimates, the predictions of uptakes were still uncertain

Conclusions

We estimated that publicly funding pelvic floor muscle training for adults with stress urinary incontinence, pelvic organ prolapse, and fecal incontinence in Ontario would result in a substantial budget increase to the province over the next 5 years. For women with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse, publicly funding pelvic floor muscle training would result in total additional costs of \$185.3 million, \$275.6 million, and \$85.8 million respectively, over the next 5 years. For men with stress urinary incontinence and fecal incontinence, publicly funding pelvic floor muscle training would result in total additional costs of \$10.8 million and \$131.1 million, respectively, over the next 5 years.

Preferences and Values Evidence

Objective

The objective of this analysis was to explore the underlying values, needs, and priorities of those who have lived experience of stress urinary incontinence, fecal incontinence, or pelvic organ prolapse, as well as patient preferences and their perceptions of pelvic floor muscle training.

Background

Exploring patient preferences and values provides a unique source of information about people's experiences of a health condition and the health technologies or interventions used to manage or treat that health condition. It includes the impact of the condition and its treatment on the person with the health condition, their family and other caregivers, and the person's personal environment. Engagement also provides insights into how a health condition is managed by the province's health system.

Information shared from lived experience can also identify gaps or limitations in published research (e.g., outcomes important to those with lived experience that are not reflected in the literature).¹⁰⁶⁻¹⁰⁸ Additionally, lived experience can provide information and perspectives on the ethical and social values implications of health technologies or interventions.

Because the needs, preferences, priorities, and values of those with lived experience in Ontario are important to consider to understand the impact of the technology in people's lives, we may speak directly with people who live with a given health condition, including those with experience of the technology or intervention we are exploring.

For this analysis, we examined the preferences and values of people with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse in 3 ways:

- A review of the quantitative evidence on patient and provider preferences and values
- An informal review of qualitative evidence from some recently published Canadian HTAs^{30,42,109,110}
- Direct engagement by Ontario Health with people with these conditions through interviews

Quantitative Evidence

Research Questions

- What is the relative preference of patients for pelvic floor muscle training compared with no treatment or other conservative treatments?
- What is the relative importance of key attributes of pelvic floor muscle training and what trade-offs between attributes are patients willing to make?

Methods

Literature Search

We performed a literature search on June 16, 2023, for quantitative preferences and value studies published since January 1, 1980, to the search date. We used the Ovid interface to search MEDLINE and the EBSCOhost interface to search the Cumulative Index to Nursing & Allied Health Literature (CINAHL). We also searched the International Network of Agencies for Health Technology Assessment (INAHTA) database of health technology assessments.

The search was based on the clinical search strategy with a methodological filter applied to limit retrieval to quantitative evidence of preferences and values (modified from Selva et al¹⁵). The final search strategy was peer-reviewed using the PRESS Checklist.⁴

We created database autoalerts in MEDLINE and CINAHL and monitored them until October 4, 2023. See Appendix 1 for our literature search strategies, including all search terms.

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text papers
- Randomized controlled trials, health technology assessments, systematic reviews, observational studies, surveys, questionnaires, discrete-choice experiments
- Utility measures: direct techniques (standard gamble, time trade-off, rating scales) or conjoint analyses (discrete-choice experiments, contingent valuation and willingness-to-pay, probability trade-off)
- Other quantitative measures, such as direct-choice techniques, decision aids, surveys, and questionnaires

Exclusion Criteria

- Animal and in vitro studies
- Nonsystematic reviews, narrative reviews, abstracts, editorials, letters, case reports, commentaries, and qualitative studies

Participants

Inclusion Criteria

- People (≥ 12 years) diagnosed with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse

Exclusion Criteria

- People ≤ 11 years of age

- Pelvic organ prolapse, urinary incontinence, or fecal incontinence not associated with pelvic floor dysfunction (e.g., urinary incontinence due to a neurological condition or pelvic cancer)

Interventions

Inclusion Criteria

- Supervised and guided pelvic floor muscle training for treatment (such as but not limited to Kegel exercises) with or without adjunct (biofeedback, weighted vaginal cones, and electrical or neuromuscular stimulation) or other conservative treatment (e.g., pessary)

Exclusion Criteria

- Pelvic floor muscle training for prevention
- Unsupervised and unguided pelvic floor muscle training (e.g., pamphlets, DVDs, online)

Comparators

Inclusion Criteria

- No comparator
- Control (i.e., no active treatment)
- Other conservative treatment (e.g., pessary)

Exclusion Criteria

- Surgery
- Pelvic floor muscle training

Outcomes

- Patient preferences
- Goals of treatment

Literature Screening

A single reviewer conducted an initial screening of titles and abstracts using Covidence⁵¹ and then obtained the full text of studies that appeared eligible for review according to the inclusion criteria. A single reviewer then examined the full-text articles and selected studies eligible for inclusion.

Statistical Analysis

Results are summarized narratively. No additional statistical analyses were conducted beyond those reported in the primary studies.

Critical Appraisal of Evidence

We did not undertake a formal critical appraisal of the included studies.

Results

Literature Search

The literature search of the quantitative evidence of preferences and values yielded 748 citations published between January 1, 1980, and June 16, 2023, including grey literature searches and after duplicates were removed. We identified 1 additional study from database alerts (monitored until October 4, 2023). In total, we identified 2 studies that met our inclusion criteria. Figure 4 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for the literature search for quantitative evidence of preferences and values.

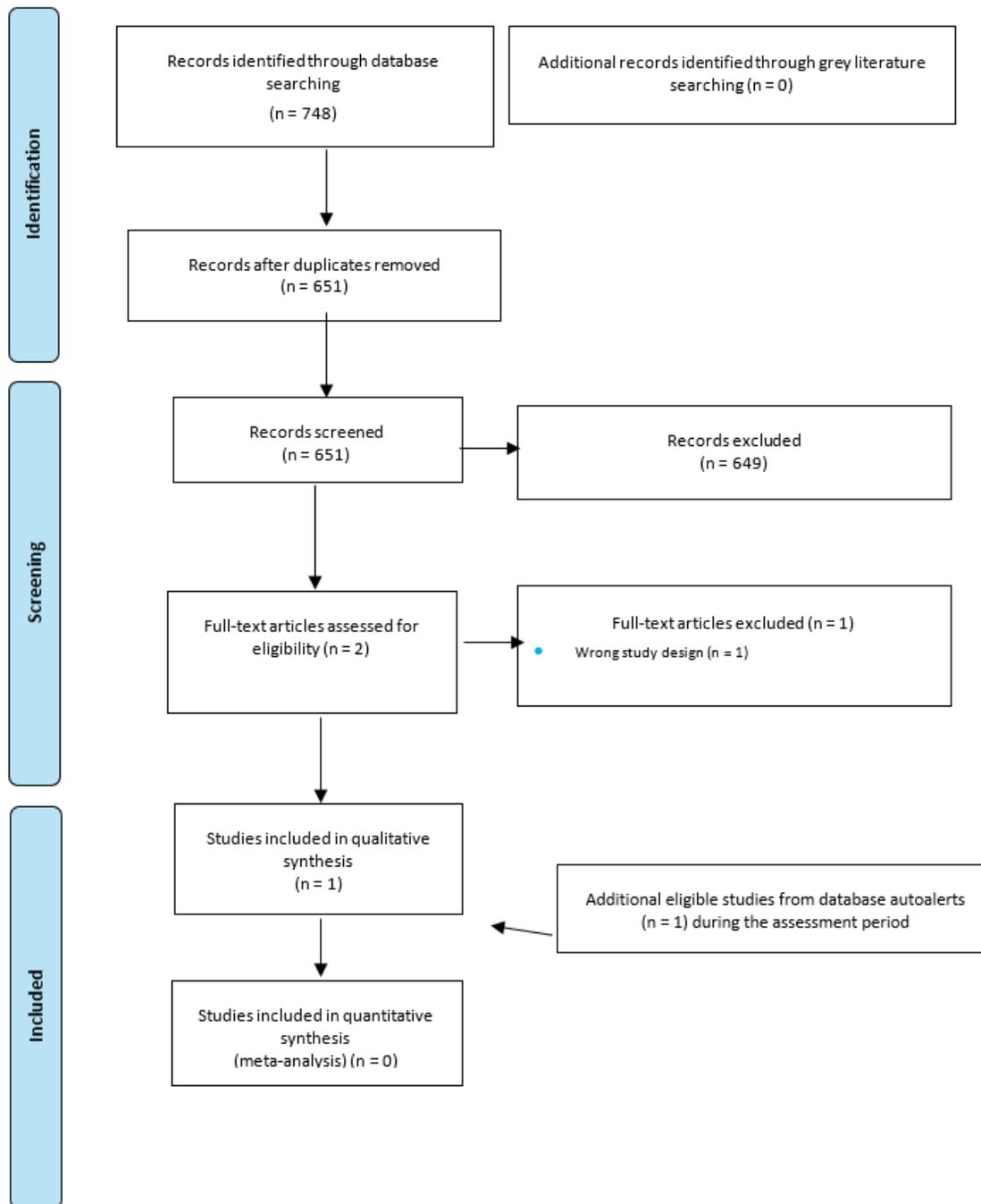


Figure 4: PRISMA Flow Diagram – Quantitative Evidence of Preferences and Values Systematic Review

PRISMA flow diagram showing the quantitative evidence of preferences and values systematic review. The database search of the preferences and values literature yielded 651 citations published between January 1, 1980, and June 16, 2023, including grey literature searches and after duplicates were removed. We screened the abstracts of the 651 identified studies and excluded 649. We assessed the full text of 1 article as well as 1 study we identified during database alerts. In the end, we included 2 articles in the qualitative synthesis.

Abbreviation: PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.⁵¹

Characteristics of Included Studies

Characteristics of the 2 included studies are shown in Table 33.

Table 33: Characteristics of Included Studies for Quantitative Evidence

Author, year	Objective	Methods	Intervention			Comparator		
			Description	n	Age, mean (SD), y	Description	n	Age, mean (SD), y
Observational single cohort								
Karantanis et al, ¹¹¹ 2014	To investigate preferences (e.g., degree to which decisions influenced by medical information, referring local general practitioners, other sources, and other factors)	Questionnaire ^a Patients with stress urinary incontinence recruited from 3 urogynecology departments	PFMT	104	49 (12)	—	—	—
Randomized controlled trial								
Limbutara et al, ¹¹² 2023	To assess whether treatment was successful based on achievement of self-determined goals	Participants, with stage 2–3 pelvic organ prolapse, asked to list 3 goals expected from treatment Primary outcome: proportion of treatment group participants for whom all 3 goals were achieved at 6 wk	PFMT IUGA protocol (exercises twice/week, 3 sets of 8–12 maximal contractions, 3 times/day) Follow-up at 2 and 6 wk: Digital examination to check whether patients contracted muscle correctly	20	65.70 (9.89)	Pessary (ring pessary with or without support and Gellhorn pessary) 2-wk follow-up: If pessary fell out or discomfort experienced, patient refitted ^c with different type or size; reviewed again after 2 wk ^d	20	68.80 (6.40)

Abbreviations: IUGA, International Urogynecology Association; PFMT, pelvic floor muscle training; SD, standard deviation; wk, weeks; y, years.

^aQuestionnaire comprised of 3 parts: questions to determine current knowledge of SUI treatments; information sheets about PFMT, tension free vaginal tape procedure, and open colposuspension; and questions asking for information about patients' preferred treatment and reasons for their choice.

^bGoals were divided into 10 categories: bladder, bowel, prolapse, pain-related, sexual, physical function, social relationships, emotional, combined goal, and other goals.

^cPessary size considered correct when physician could place finger between pessary and vaginal wall, prolapse reduced to above hymen, patient felt comfortable, and pessary retained during Valsalva manoeuvre and coughing in both supine and standing positions.

^dIf pessary fell out or discomfort experienced, fitting deemed unsuccessful.

Patient Preferences

Karantanis et al¹¹¹ found that pelvic floor muscle training was the preferred management choice for 68 out of 104 (65%) women with stress urinary incontinence, followed by tension-free vaginal tape (27 women [26%]) and colposuspension (6 women [6%]). The information sheets were the main basis for these choices in 86 out of 104 (83%) women.

For patients who preferred pelvic floor muscle training, 34 out of the 68 (50%) reported noninvasiveness and low risk as the main reasons for their choice, 16 women felt they should try a conservative treatment before considering surgery (without mention of risk or invasiveness of surgery), 5 women thought their urine leakage was too mild to consider surgery, and 4 women wanted to avoid possible cesarean section in the event of a subsequent pregnancy.

Of note, Health Canada issued notices to hospitals in 2014 regarding complications related to tension free vaginal tape for stress urinary incontinence.¹¹³ Karantanis et al¹¹¹ included tension-free vaginal tape as a treatment option. Women's preferences regarding tension free vaginal tape may have changed after learning about the 2014 Health Canada notices. Limitations of the study¹¹¹ include lack of information about patient preferences after undergoing treatment, and no information was reported about how questionnaires were administered, collected, or assessed.

Achievement of Treatment Goals

Limbutara et al¹¹² determined that, at 6 weeks, significantly more people ($P = .01$) with pelvic organ prolapse achieved their goals in the vaginal pessary group (14 out of 20 [70%]) compared with those in the pelvic floor muscle training group (6 out of 20 [30%]); however, dropouts, complications, whether any patients had unsuccessful pessary fittings, how patient goals were collected, and who assessed the results were not reported

Discussion

Karantanis et al¹¹¹ showed that noninvasiveness of an intervention is an important factor related to treatment choice for women with stress urinary incontinence.

The mechanism of action of conservative treatments may also play a role in how patients view achievement of their treatment goals, at least with respect to patients with pelvic organ prolapse. Limbutara et al¹¹² suggested that their results may be explained by pessaries providing mechanical support and offering prompt reduction of pelvic organ prolapse symptoms and restoration of normal anatomy in comparison with pelvic floor muscle training, with which relief of pelvic organ prolapse symptoms may take longer (weeks) to manifest.

Conclusions

We found evidence that pelvic floor muscle training was the preferred option for most women with stress urinary incontinence in a study¹¹¹ about treatment choices, but in a study with people with pelvic organ prolapse,¹¹² a pessary helped more people achieve their treatment goals compared with pelvic floor muscle training.

Qualitative Evidence

We also leveraged existing research to gain additional insights about lived experiences^{30,42} and to explore the perspectives of people who have undergone prostatectomy with incontinence as a side effect.^{109,110} The following 4 HTAs explored the perspectives and experiences of patients through direct patient engagement or qualitative review.

- INESSS HTA: Perineal and pelvic rehabilitation for the prevention and treatment of pelvic floor dysfunctions⁴²

- University of Calgary HTA: Open and Minimally Invasive Prostatectomy¹⁰⁹
- CADTH HTA: Prostatectomy for People with Prostate Cancer¹¹⁰
- Ontario Health HTA: Vaginal Pessaries for Pelvic Organ Prolapse or Stress Urinary Incontinence³⁰

We synthesized our findings from this informal review with our findings from direct patient engagement (see Results).

Direct Patient Engagement

Methods

Partnership Plan

The partnership plan for this health technology assessment focused on consultation to examine the experiences of people with pelvic organ prolapse, stress urinary incontinence, and fecal incontinence and those of their families and other care partners. We engaged people via face-to-face and phone interviews and an online survey.

No relevant equity issues were identified in this health technology assessment; as a result, we did not carry out specific engagement initiatives for distinct populations.

We used a qualitative interview and online survey, as this method of engagement allowed us to explore the meaning of central themes in the experiences of people with pelvic organ prolapse, stress urinary incontinence, and fecal incontinence as well as those of their families and caregivers.¹¹⁴ The sensitive nature of exploring people's experiences of a health condition and their quality of life are other factors that support our choice of an interview and survey methodology.

Participant Outreach

We used an approach called purposive sampling,¹¹⁵⁻¹¹⁸ which involves actively reaching out to people with direct experience of the health condition and health technology or intervention being reviewed. We approached a variety of partner organizations, including physiotherapy clinics to spread the word about this engagement activity and to contact people with pelvic organ prolapse, stress urinary incontinence, and fecal incontinence family members, and caregivers, including those with experience of pelvic floor muscle training.

Inclusion Criteria

We sought to speak with people and their caregivers who have been actively managing pelvic organ prolapse, stress urinary incontinence and fecal incontinence. These people were not required to have had direct experience with pelvic floor muscle training to participate. While we did not carry out engagement with distinct populations, we did seek broad geographic, cultural, and socioeconomic representation to explore possible equity issues in accessing treatment for pelvic organ prolapse stress urinary incontinence, and fecal incontinence.

Exclusion Criteria

We did not set specific exclusion criteria.

Participants

We engaged with 21 people (15 interview participants and 6 survey respondents). Of the 21 individuals, there were 6 with stress urinary incontinence, 10 with pelvic organ prolapse, 1 with fecal incontinence, 3 with pelvic organ prolapse and stress urinary incontinence, 1 with all 3 conditions; 4 individuals had more than 1 condition. Two of the 6 diagnosed with stress urinary incontinence were male perspectives. Many participants (15 out of 21) had direct experience with pelvic floor muscle training.

Approach

At the beginning of the interview and survey, we explained the role of our organization, the purpose of this health technology assessment, the risks of participation, and how participants' personal health information would be protected. We gave this information to participants both verbally and in a letter of information (Appendix 7). We then obtained participants' verbal consent before starting the interview. With participants' consent, we audiorecorded and transcribed the interviews.

Interviews lasted approximately 45 to 60 minutes. The interview and survey were loosely structured and consisted of a series of open-ended questions. Questions were based on a list developed by the Health Technology Assessment International Interest Group on Patient and Citizen Involvement with Health Technology Assessment.¹¹⁹ Questions focused on the impact of pelvic organ prolapse, stress urinary incontinence, and fecal incontinence on the quality of life of people with these health conditions, their experiences with treatments to manage or treat the condition, their experiences with pelvic floor muscle training, and their perceptions of the benefits or limitations of pelvic floor muscle training. For family members and caregivers, questions focused on their perceptions of the impact of pelvic organ prolapse, stress urinary incontinence, and fecal incontinence and treatments on the quality of life of the person with any of these health conditions, as well as the impact of the person's health condition and treatments on the family members and caregivers themselves. See Appendix 8 for our interview guide.

Data Extraction and Analysis

We used a modified version of a grounded-theory methodology to analyze interview transcripts, and survey results. The grounded-theory approach allowed us to organize and compare information on experiences across participants. This method consists of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting, analyzing, and comparing information.^{120,121} We used qualitative data analysis software (NVivo¹²²) to identify and interpret patterns in the data. The patterns we identified allowed us to highlight the impact of pelvic organ prolapse, stress urinary incontinence, and fecal incontinence and treatments on the people with pelvic organ prolapse, stress urinary incontinence, and fecal incontinence, family members, and caregivers we interviewed.

Results

Symptoms

Participants described the symptoms that they experienced living with pelvic organ prolapse, stress urinary incontinence, and fecal incontinence. People with pelvic organ prolapse spoke about symptoms that included a bulge protruding from the vagina, pain, discomfort, pelvic pressure, back pain, and difficulty emptying bowels. People with stress urinary incontinence and fecal incontinence spoke about having unexpected urine and fecal leakage. Incontinence symptoms were also experienced by some of the participants who suffered from pelvic organ prolapse:

The symptoms were a lot of heaviness, discomfort, sensitivity, pain on touch of, like, the vaginal opening.

I can feel the bulge in my vagina all day long, which, as you can imagine, in addition to being uncomfortable, is also psychologically very difficult.

I would have incontinence if I wasn't immediately near a bathroom because I would get no signals that I needed to have a bowel movement until it was immediate.

Impact on Day-to-Day Life

Participants spoke about the struggles they face in managing their conditions and described their symptoms having a profound impact on their day-to-day lives. Physical challenges they faced included mobility issues brought on by their condition, such as difficulty walking, standing, and bending. In addition, these mobility issues made conducting simple daily errands difficult:

I would get halfway through a load of dishes and then have to sit down, and it was really impairing my capacity to get out of the house.

It impacted my work because I couldn't sit for very long because I was in pain. I couldn't exercise. I couldn't almost do anything. It ruled my life.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

I stopped doing certain things. Like even to go for lunch with my friends at work, I knew I could only walk around the building across from us. Like, I couldn't go for my normal walks.

Strenuous activities such as exercising and lifting heavy objects were difficult or not possible due to discomfort, pressure, or the incontinence that these activities would cause. In some cases, participants avoided or restricted their activity levels due to the fear of the possible consequences:

I didn't want to do any exercise of any kind.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

I've completely stopped exercising because I'm terrified of making it worse...I'm terrified of doing anything. For a long time, I was afraid to even take my son out for walks, because I was worried that would make everything worse.

Although some of the people we spoke to were retired, those who were employed reported on how their condition impacted their work life in many ways. They reflected on the difficulties of working in an office environment due to the constant sitting and the negative repercussions they faced due to the limitations imposed by their symptoms:

I had to sit more. I had to lay on the floor at work to do my [pelvic floor] exercises, to keep everything at bay.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

I'm back at work now and we have a system where we have laptops we can take home and I can't carry a laptop back and forth every day, because that impacts on my prolapse. The way I sit in the office all day isn't great. At least when I was

home on [maternity] leave, I could lie down...But now I'm in the office 8 hours a day, sitting, with gravity pulling everything down the entire time.

I did miss some work due to the back pain with the prolapse initially. Now I'm on an attendance awareness program, which is totally humiliating because I've never had any issues with attendance before.

Some people avoided or limited their participation in social engagements and hobbies such as singing, dancing, and sports. One reason for this was the physical limitations that resulted from their condition:

I used to do folk dancing...but there's a lot of hopping. It kind of puts a damper on everything.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

It was still affecting my activities of daily living. I'm a very physical person and I dance. I had to change from my tapping class to jazz, because I couldn't tap. And tap is my joy. I love tapping.

I sing Wednesday nights and I couldn't stand for the 2 hours. I had to sit on a chair to sing, because I couldn't stand the whole time. I'd start and then I'd have to sit. So that was embarrassing.

People with incontinence spoke about the need to be near a washroom as an additional reason for their reluctance to engage in social activities. Participants also mentioned the impact on social dynamics with feelings of embarrassment in social setting should they suffer from incontinence:

I worry about accidents and smelling since I have no idea when I've gone (little awareness of any urge). My social life often comes to a standstill. I cannot go to most restaurants or enjoy family meals because of my restrictive diet.

I'm anxious about going into public spaces because if I don't have a bowel movement in the morning and I have one in the middle of the day.

The CADTH found that participants with urinary incontinence who had undergone prostatectomy had differing views on living with incontinence as a side effect, with some expressing concern that their condition could get worse:

[T]he hard part is that you feel the leaking, you cannot go out. Depending on the place, I don't even go because you have to change the diaper all the time.¹¹⁰

[side effects] are not important compared to dying. So, you know, the rest of it is immaterial. If I have to wear Depends [incontinence underwear] the rest of my life, then so be it.¹¹⁰

It was distressing me quite a bit, the continence side of it, to the point where I would occasionally think to myself, 'why the hell did I bother with this operation, why didn't I just let it go, and when things happen, things happen, you know!¹¹⁰

Impact on Relationships

Several participants spoke about the impact of their conditions on their relationships with their partners. Sexual intercourse was painful or uncomfortable which put a strain on their relationships with their partners. There was also an increase reliance on their partners due to their symptoms restricting

which errands they could do. Family planning was impacted due to hesitation because of fear of what being pregnant again could mean to their condition in the future:

Intercourse is always uncomfortable, which affects my degree of affection sharing. I feel incomplete as a partner and can notice a distance grow between us as I'm not as responsive as I wish to be.

We've talked about adopting or not having another child.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰: [My husband] was very frustrated and he would get angry with me, and then I'd get defensive or quiet, and then we seemed to [drift] apart. For sure we didn't talk as much. He would go out [alone] more...then, of course, you get angry at yourself, and then you're frustrated, and then you're mad at them and it's not their fault. It's a whole series of emotions.

Participants also reflected on how their conditions impacted their relationships with their children or grandchildren. They spoke about having missed experiences with their children such as not being able to lift their child, chase them around house, or jump on a trampoline:

I have a young child that I can't jump on the trampoline with like I used to do.

I was imagining [what] maternity leave was gonna look like being out for a lot of hikes and running with my daughter.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

It's changed the way that I can interact with my son. I'll never be able to run around on the playground with him, or do anything like that, because it will damage my prolapse further. So it has completely changed that relationship.

Impact on Mental Health

Participants described how their condition and living with the discomfort and activity restrictions impacted their mental health. Participants reported suffering from anxiety, depression, and fear brought on by their symptoms. They also mentioned increased hypervigilance – constantly thinking about their symptoms. Additionally, they described the negative impact on their self-confidence and the stigma they experience:

There was just a lot of fear and anxiety and uncertainty about what was going on with my body and how to take care of myself and worried that I would never be able to get back to being physically active again. It was extremely distressing and extremely emotional time that lasted a year and a half after giving birth.

It's alienating you and segregating you and isolating you, which we all know isolation is a huge part of mental health struggles.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

I've had issues with anxiety and depression for a long time and it just made me deeply depressed because I felt like my body had betrayed me and I felt crippled. Literally. And the worst part is nobody can see it. I looked perfectly healthy.

Stigma, embarrassment, and humiliation have been described in other HTAs^{109,110}:

[I]t was a very heavy burden for me for my pants to become wet in front of my child, my wife, my son-in-law; I can say I felt terribly embarrassed, the feeling just can't be described.¹¹⁰

Well, I use [the pads] when I'm at work. Because obviously, it's more socially embarrassing when [the time comes to urinate] and you wet yourself.¹⁰⁹

[P]eople already feel uncomfortable and unhappy by the situation and the clothing and the devices that are being offered are so pathetic looking that it makes you even feel worse.¹¹⁰

Care Journey

Participants spoke about the stigmatizing nature of their condition and the embarrassment and shame they felt bringing up their condition to their care provider. A majority commented on having no prior knowledge of pelvic organ prolapse and the diagnosis being unexpected and traumatic. There was also anger and frustration about the lack of awareness and information on pelvic organ prolapse:

I saw the tissues bulging in the opening to my vagina and I thought it was gross and I panicked. I thought I had cancer.

It's a secret nobody wants to talk about it. We're ashamed of it, but it affects so many of us...There's a shame associated with it, and there shouldn't be.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

Angry is what I felt that this information is not more public, that it's not more accessible, that you know you have to be so ashamed of the condition in the first place that you don't even bring it up to your doctor.

When trying to get a diagnosis, participants expressed lack of support from their care providers where, in some cases, their concerns weren't taken seriously or were dismissed:

This particular doctor and the fact that he laughed at half my questions that I was very serious about.

I went to my doctor, and I shared these concerns with him. He didn't have anything helpful to say.

People who were referred to specialists or pessary clinics mentioned long wait times – from 6 months to over 1 year. They stated they were not provided any support on how to manage their symptoms while they waited for a consultation. Additionally, participants spoke about experiences where they were misdiagnosed or given conflicting information by different specialists:

They referred me to a gastroenterologist which took a year to get into, so still again suffering with all of these symptoms not having any sort of help whatsoever. Once I got in to see the gastroenterologist. He did not even do any sort of physical exam and just assumed it was IBS [irritable bowel syndrome] and treated me as such.

It took 16 to 18 months to get a pessary. When women are living in extreme discomfort to the point that many of them are feeling suicidal.

I still haven't seen a urogynecologist about it. The wait times are abominably long.

Treatment Option: Pessary

People who had used a pessary spoke about their experience. These participants had a variety of experiences with who fitted their pessaries – pelvic floor physiotherapists, health care professionals, or nurses. Participants noted that the preference to use a pessary as a form of treatment is a very personal decision. Several people mentioned using a pessary in combination with pelvic floor muscle training. Comfort was an important decision factor, and participants described that there was a trial-and-error period in using a pessary (i.e., finding one that was able to manage their symptoms, having the ability to manage day to day use, such as cleaning, removing, and inserting the pessary):

I have tried pessaries. They're very uncomfortable for me.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

It's easy to do. If you've ever used a diaphragm, it's no more difficult than that— or probably less. It's easy to do if you're mobile enough to be able to reach.

The pessary has made an enormous difference in my life. It's incredible. I couldn't walk half a block without having to sort of sit down and pull my muscles in just to relieve the pressure...

Participants who had not been comfortable using pessaries cited their concerns about infection, erosion, and comfort:

I also learned that pessaries can irritate your skin tissues and you can get erosion. That's a whole other set of problems.

Similar experiences were reported by participants in Ontario Health's HTA on vaginal pessaries³⁰:

The second [province] doctor I saw tried me with a cube pessary. It was excruciating. It was horrible! Fortunately, I didn't leave the hospital with it, so I turned it back in and said this isn't going to work.

Treatment Option: Surgery

In Ontario Health's HTA on vaginal pessaries,³⁰ when participants were asked about undergoing surgery as a treatment option to manage their symptoms, they spoke about considering surgery depending on the severity of symptoms and there was hesitancy and fear about having surgery due to the invasiveness. All participants considered it as a last resort that they would consider if they exhausted all options:

I've heard horror stories from people that have had surgery.

I just felt that that was very invasive, removing an organ and I felt it was very invasive for the condition I had. While my condition was uncomfortable, it was not life-threatening or anything. So, I felt that the surgical option seemed extreme to me.

A few participants in Ontario Health's HTA on vaginal pessaries³⁰ had experience undergoing surgery and stated it either failed or brought on another prolapse:

I had the surgery, but it just didn't seem to really help, so it seemed at the beginning but not after a month or so, it's back. And I had a lot of pain after the surgery.

Treatment Option: PFMT

Many participants had experience with pelvic floor muscle training. Unfortunately, there were no male participants who had experience with pelvic floor muscle training. Participants spoke about the importance of finding a pelvic floor physiotherapist that they are comfortable with but also has the level of expertise to manage their condition. People with young children stated they had difficulties getting to appointments due to the difficulties in making childcare arrangements:

I was diagnosed with stage 3 [pelvic organ prolapse], I've been to 3 different pelvic floor physical therapists.

It's very intimate thing. It depends on the level of training.

People with experience with pelvic floor muscle training spoke about how they were provided tailored guidance on how to properly engage their pelvic floor muscles, how to safely exercise and lift heavy objects, and how to prevent the worsening of their symptoms as well as posture and breathing techniques to manage their symptoms:

I never realized that breathing was so important and how you breathe when you do your kegels.

She's helping me to do that and feel like I can go back to lifting and do it with confidence, even though I have this condition.

She had me doing exercise therapy and to help strengthen my core that had probably the biggest impact on the pelvis.

She taught me things that I didn't even know about myself. You have these 3 muscle groups, and you can actually isolate them.

A couple participants stated that they tried pelvic floor muscle training, and it didn't treat their symptoms – one stated pelvic floor muscle training might have made their symptoms worse:

I did see a pelvic floor specialist. When she did try to help me, but I think it was basically too far gone.

Pelvic floor muscle therapy did not help...in fact, I think it made it worse.

Many people stated they had a positive experience with pelvic floor muscle training and that it reduced or alleviated their symptoms. They commented on the significant improvement in their quality of life such as gaining their independence back, being able to go back to running errands, exercising. They also noted the positive impact on their mental health in reducing their depression, anxiety, and the emotional toll of living with their condition:

I can go on long walks. I can go for grocery trip without becoming uncomfortable. I'm still able to pick up my son...So it's giving me a lot of my life and freedom and independence back. I'm not relying on my husband as much.

I've had a really positive experience. It's obviously curbed my symptoms to a level that is very manageable, and I would say like basically fixed. it's given me the quality of life back.

I can have sex again without it hurting and that I can do things again without having to stop has taken away the mental distress component.

Barriers to Accessing Pelvic Floor Muscle Training

One of the main barriers mentioned in accessing pelvic floor muscle training was lack of awareness about this treatment option. Many mentioned not being aware of or told that pelvic floor muscle training was a treatment option for their condition by their care providers. Many found out about pelvic floor muscle training through internet searches about their condition and online support groups, or by word of mouth:

I knew nothing about pelvic floor therapy. I had been to see the doctor I had been to see the local gynecologist for the troubles [and] was told everything was fine. There's nothing we can do. Never mentioned the [pelvic] floor therapist.

Nobody has spoken to me about anything...My family doctor told me I had a prolapse. He did not say what grade it was. He did not say what I needed. He just said I'm going to refer you to a gynecologist. Did not mention physio.

Thankfully, I'm on a couple of Facebook groups that have helped facilitate some of that knowledge for me, and I did my own call around to several of the physios.

Many participants stated that high cost and the multiple sessions required were barriers. Participants without insurance either mentioned the financial strain that this had caused or that they had avoided pelvic floor muscle training:

Cost of pelvic floor physiotherapy was the biggest and only hurdle. I couldn't afford \$100 to \$150 for the sessions as I'm on a fixed low income.

Participants with insurance also stated that cost was a barrier due to insurance not covering the full cost or reaching the maximum. There were also concerns about not having enough coverage for other physiotherapy services they needed (for other conditions such as knee or back pain):

They're pretty expensive. I think they might have been like \$95.00 a session. They were pretty pricey. Between me and my husband's insurance, it paid for half maybe per visit...

It was quite expensive. I think my insurance didn't pay for all of it.

Participants also mentioned the varying levels of expertise among pelvic floor physiotherapists. Male participants highlighted this as a barrier due to the limited expertise of male pelvic floor muscle training available. Female participants mentioned the need to consult multiple pelvic floor physiotherapists until they found someone they were comfortable with:

They were essentially wasted appointments because she was not a specialist, she had taken some courses and I have since learned that in this area you want somebody who is a certified pelvic floor physiotherapist.

I was diagnosed with stage 3 [pelvic organ prolapse], I've been to 3 different pelvic floor physical therapists.

Geographic barriers were mentioned by some participants who lived outside of urban areas. Male participants mentioned the limited availability of male pelvic floor muscle training across Ontario.

We live in a smaller city, and there are very few options available.

I am not really looking forward to a 3-hour drive each week for a 1-hour appointment.

Discussion

Participants described the burden of their condition and its disruption to their daily life, mental health, employment, and relationships. They also discussed the benefits of pelvic floor muscle training – managing their symptoms and improving their quality of life without the need for surgery.

A limitation of our analysis was that no male perspectives with pelvic floor muscle training experience were included and limited perspectives from Northern Ontario and remote locations.

Conclusion

Participants emphasized that the choice of treatment options is based on personal criteria and preferences. Participants reported pelvic floor muscle training as being an effective conservative treatment option to manage their symptoms. People spoke about the positive impact of pelvic floor muscle training on their social, emotional, and physical well-being. Barriers to accessing pelvic floor muscle training in Ontario included lack of awareness about pelvic floor muscle training as a treatment option, cost of pelvic floor muscle training, limited access (due to geographical location, and in some cases, the lack of health care professionals trained to deliver pelvic floor muscle training).

Preferences and Values Evidence Discussion

Robust patient preferences and values evidence allowed us to learn about the lived experiences of people with stress urinary incontinence, fecal incontinence, and pelvic organ prolapse and examine and compare their perceptions of different types of treatments.

Invasiveness (i.e., whether a treatment was conservative or not) was an important factor for women choosing between treatment options for stress urinary incontinence – this was a common theme in both quantitative and qualitative findings. In general, people with stress urinary incontinence, fecal incontinence, or pelvic organ prolapse had a strong preference for conservative treatments such as pelvic floor muscle training and viewed surgery as a last resort option, a sentiment expressed in both the INESSS report, the quantitative evidence and through direct patient engagement.

One of the limitations of direct patient engagement was low representation from the male perspective and no representation from those who experience stress urinary incontinence after prostatectomy. The qualitative evidence leveraged the University of British Columbia and CADTH's health technology assessments on prostatectomy allowed for the examination of the quality of life of those who experience stress urinary incontinence after prostatectomy. However, neither of these reports touched on treatments for stress urinary incontinence. Our direct patient engagement did include 2 male

perspectives, and both had no experience with pelvic floor muscle training but were open to trying it to manage their stress urinary incontinence.

Equity Considerations

No equity considerations were evaluated in the Quantitative Preferences Evidence.

Preferences and Values Evidence Conclusions

In an observational single-cohort study, pelvic floor muscle training was the preferred management choice of 65% of women with stress urinary incontinence. In a randomized controlled trial with unclear methodological details, after 6 weeks more people with pelvic organ prolapse who used a pessary achieved their treatment goals compared with people who underwent pelvic floor muscle training.

The qualitative and direct patient engagement evidence showed that pelvic floor dysfunction can cause a number of symptoms that negatively affect a person's quality of life. There were positive perceptions regarding pelvic floor muscle training and its ability to improve symptoms and quality of life. Treatment choice is highly based on individual preferences, but in general, most people wanted to avoid having surgery when possible.

Conclusions of the Health Technology Assessment

Stress Urinary Incontinence

Women

For women with stress urinary incontinence, in comparison with no treatment, pelvic floor muscle training likely improves symptoms and may improve quality of life (with very little certainty regarding the evidence) and satisfaction.

When compared with other conservative treatments such as pessary electrical stimulation, magnetic stimulation, or vaginal cone, there was little to no difference in symptom improvement. Similarly, there was little to no difference in other outcomes for which evidence was available between these treatments and pelvic floor muscle training alone or as an adjunct – satisfaction (pessary), quality of life (electrical stimulation and vaginal cone), and complications (magnetic stimulation), although there was uncertainty regarding the evidence from comparisons with electrical stimulation, magnetic stimulation, and vaginal cone therapies. There was also evidence that pelvic floor muscle training with biofeedback may improve quality of life in comparison with some – electrical stimulation (with some uncertainty regarding the evidence) – but not other – vaginal cone – conservative treatments. Likewise, there was evidence, with some uncertainty, that pelvic floor muscle training may improve quality of life in comparison with usual care during the prenatal period.

The economic evidence review indicated that pelvic floor muscle training was likely cost-effective in comparison with other nonsurgical interventions. Publicly funding pelvic floor muscle training for this clinical population would likely cost approximately \$185.3 million over the next 5 years.

People with whom we spoke shared that, in their experience, pelvic floor muscle training was an effective treatment option to manage stress urinary incontinence symptoms.

Men

For men with stress urinary incontinence after prostate surgery, there may be little to no difference between pelvic floor muscle training (with or without biofeedback) and no treatment in terms of symptoms, quality of life, or the occurrence of complications; there was very little certainty regarding the evidence.

The economic evidence review indicated that pelvic floor muscle training was likely not cost-effective for adult men with urinary incontinence after prostate surgery when compared with standard care. Publicly funding pelvic floor muscle training for adult men with stress urinary incontinence would likely cost approximately \$10.8 million over the next 5 years.

Fecal Incontinence

For men or women with fecal incontinence, the clinical evidence showed that there may be little to no difference in symptom improvement between standard care and pelvic floor muscle training, but there was very little certainty in the evidence.

We did not identify any studies on pelvic floor muscle training for women or men with fecal incontinence in the economic review. The cost-effectiveness of pelvic floor muscle training for women or men with fecal incontinence is unknown. Publicly funding pelvic floor muscle training for adult women and men with fecal incontinence would likely cost approximately \$275.6 and \$131.1 million, respectively, over the next 5 years.

Pelvic Organ Prolapse

For women with pelvic organ prolapse, in comparison with no treatment, pelvic floor muscle training likely reduces symptom severity, improves quality of life, and improves patient satisfaction. In comparison with treatment with a pessary, pelvic floor muscle training may not reduce symptom severity or improve sexual function, but it may result in fewer complications (however, there was little certainty in the evidence regarding complications).

The cost-effectiveness of pelvic floor muscle training for women with pelvic organ prolapse compared with no treatment was uncertain, and pelvic floor muscle training was likely not cost-effective compared with treatment with a pessary. Publicly funding pelvic floor muscle training for this clinical population would likely cost approximately \$85.8 million over the next 5 years.

We did not identify any studies on pelvic floor muscle training for men or men with pelvic organ prolapse (i.e., rectal prolapse) in the economic review.

Pelvic Floor Dysfunction

Several people spoke about the positive impact pelvic floor muscle training had on their social, emotional, and physical well being; however, cost, lack of awareness of this treatment option, or difficulty finding trained health care professionals in their area are barriers that some people in Ontario may face.

Abbreviations

CI: confidence interval

GRADE: Grading of Recommendations Assessment, Development, and Evaluation

INESSS: Institut national d'excellence en santé et en services sociaux

NICE: National Institute for Health and Care Excellence

OR: odds ratio

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses

QALYs: quality-adjusted life-year

RR: risk ratio

SD: standard deviation

Glossary

Budget impact analysis: A budget impact analysis estimates the financial impact of adopting a new health care intervention on the current budget (i.e., the affordability of the new intervention). It is based on predictions of how changes in the intervention mix will impact the level of health care spending for a specific population. Budget impact analyses are typically conducted for a short-term period (e.g., 5 years). The budget impact, sometimes referred to as the net budget impact, is the estimated cost difference between the current scenario (i.e., the anticipated amount of spending for a specific population without using the new intervention) and the new scenario (i.e., the anticipated amount of spending for a specific population following the introduction of the new intervention).

Cost–benefit analysis: A cost–benefit analysis is a type of economic evaluation that expresses the effects of a health care intervention in terms of a monetary value so that these effects can be compared with costs. Results can be reported either as a ratio of costs to benefits or as a simple sum that represents the net benefit (or net loss) of one intervention over another. The monetary valuation of the different intervention effects is based on either prices that are revealed by markets or an individual or societal willingness-to-pay value.

Cost-effective: A health care intervention is considered cost-effective when it provides additional benefits, compared with relevant alternatives, at an additional cost that is acceptable to a decision-maker based on the maximum willingness-to-pay value.

Cost-effectiveness acceptability curve: In economic evaluations, a cost-effectiveness acceptability curve is a graphical representation of the results of a probabilistic analysis. It illustrates the probability of health care interventions being cost-effective over a range of willingness-to-pay values. Willingness-to-pay values are plotted on the horizontal axis of the graph, and the probability of the intervention of interest and its comparator(s) being cost-effective at corresponding willingness-to-pay values is plotted on the vertical axis.

Cost-effectiveness analysis: Used broadly, “cost-effectiveness analysis” may refer to an economic evaluation used to compare the benefits of 2 or more health care interventions with their costs. It may encompass several types of analysis (e.g., cost-effectiveness analysis, cost–utility analysis). Used more specifically, “cost-effectiveness analysis” may refer to a type of economic evaluation in which the main outcome measure is the incremental cost per natural unit of health (e.g., life-year, symptom-free day) gained.

Cost-effectiveness plane: In economic evaluations, a cost-effectiveness plane is a graph used to show the differences in cost and effectiveness between a health care intervention and its comparator(s). Differences in effects are plotted on the horizontal axis, and differences in costs are plotted on the vertical axis.

Cost-minimization analysis: In economic evaluations, a cost-minimization analysis compares the costs of 2 or more health care interventions. It is used when the intervention of interest and its relevant alternative(s) are determined to be equally effective.

Cost–utility analysis: A cost–utility analysis is a type of economic evaluation used to compare the benefits of 2 or more health care interventions with their costs. The benefits are measured using

quality-adjusted life-years, which capture both the quality and quantity of life. In a cost–utility analysis, the main outcome measure is the incremental cost per quality-adjusted life-year gained.

Decision tree: A decision tree is a type of economic model used to assess the costs and benefits of 2 or more alternative health care interventions. Each intervention may be associated with different outcomes, which are represented by distinct branches in the tree. Each outcome may have a different probability of occurring and may lead to different costs and benefits.

Deterministic sensitivity analysis: Deterministic sensitivity analysis is an approach used to explore uncertainty in the results of an economic evaluation by varying parameter values to observe the potential impact on the cost-effectiveness of the health care intervention of interest. One-way sensitivity analysis accounts for uncertainty in parameter values 1 at a time, whereas multiway sensitivity analysis accounts for uncertainty in a combination of parameter values simultaneously.

Discounting: Discounting is a method used in economic evaluations to adjust for the differential timing of the costs incurred and the benefits generated by a health care intervention over time. Discounting reflects the concept of positive time preference, whereby future costs and benefits are reduced to reflect their present value. The health technology assessments conducted by Ontario Health use an annual discount rate of 1.5% for both future costs and future benefits.

Dominant: A health care intervention is considered dominant when it is more effective and less costly than its comparator(s).

EQ-5D: The EQ-5D is a generic health-related quality-of-life classification system widely used in clinical studies. In economic evaluations, it is used as an indirect method of obtaining health state preferences (i.e., utility values). The EQ-5D questionnaire consists of 5 questions relating to different domains of quality of life: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each domain, there are 3 response options: no problems, some problems, or severe problems. A newer instrument, the EQ-5D-5L, includes 5 response options for each domain. A scoring table is used to convert EQ-5D scores to utility values.

Equity: Unlike the notion of equality, equity is not about treating everyone the same way.¹²³ It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

Equity-deserving groups: Those who exhibit the socially stratifying characteristics identified in the PROGRESS-Plus framework.⁵² These characteristics involve:

- Place of residence (e.g., rural and remote populations)
- Race/ethnicity/culture (e.g., First Nations, Métis, and Inuit populations, immigrant populations, and linguistic minority populations)
- Occupation or labour-market experiences more generally (e.g., those in “precarious work” arrangements like minimum-wage, seasonal, or part-time work)
- Gender
- Religion

- Educational level (e.g., health literacy)
- Socioeconomic status (e.g., economically disadvantaged populations)
- Social capital/social exclusion (e.g., citizenship/residence)
- Personal characteristics associated with discrimination (e.g., age, disability, sexual orientation)
- Time-dependent relationships (e.g., leaving the hospital, in respite care)

Extended dominance: A health care intervention is considered to be extendedly dominated when it has an incremental cost-effectiveness ratio higher than that of the next most costly or effective comparator. Interventions that are extendedly dominated are ruled out.

Health inequity: Health inequities are avoidable inequalities in health between groups of people within countries and between countries.¹²⁴ These inequities arise from inequalities within and between societies. Social and economic conditions and their effects on people’s lives determine their risk of illness and the actions taken to prevent them becoming ill or treat illness when it occurs.

Health-related quality of life: Health-related quality of life is a measure of the impact of a health care intervention on a person’s health. It includes the dimensions of physiology, function, social life, cognition, emotions, sleep and rest, energy and vitality, health perception, and general life satisfaction.

Health state: A health state is a particular status of health (e.g., sick, well, dead). A health state is associated with some amount of benefit and may be associated with specific costs. Benefit is captured through individual or societal preferences for the time spent in each health state and is expressed in quality-adjusted weights called utility values. In a Markov model, a finite number of mutually exclusive health states are used to represent discrete states of health.

Health Utilities Index Mark 3 (HUI3): The HUI3 is a generic health-related quality-of-life classification system widely used in clinical studies. In economic evaluations, it is used as an indirect method of obtaining health state preferences (i.e., utility values). The HUI3 was developed in Canada and is used in major Canadian population health surveys. The HUI3 comprises 8 attributes: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain and discomfort. Each attribute is associated with 5 or 6 defined functional levels, thus producing a total of 972,000 unique health states. A predefined scoring formula is used to convert HUI3 scores to utility values.

Incremental cost: The incremental cost is the additional cost, typically per person, of a health care intervention versus a comparator.

Incremental cost-effectiveness ratio (ICER): The incremental cost-effectiveness ratio (ICER) is a summary measure that indicates, for a given health care intervention, how much more a health care consumer must pay to get an additional unit of benefit relative to an alternative intervention. It is obtained by dividing the incremental cost by the incremental effectiveness. Incremental cost-effectiveness ratios are typically presented as the cost per life-year gained or the cost per quality-adjusted life-year gained.

Ministry of Health perspective: The perspective adopted in economic evaluations determines the types of costs and health benefits to include. Ontario Health develops health technology assessment reports from the perspective of the Ontario Ministry of Health. This perspective includes all costs and health benefits attributable to the Ministry of Health, such as treatment costs (e.g., drugs, administration,

monitoring, hospital stays) and costs associated with managing adverse events caused by treatments. This perspective does not include out-of-pocket costs incurred by patients related to obtaining care (e.g., transportation) or loss of productivity (e.g., absenteeism).

Probabilistic analysis: A probabilistic analysis (also known as a probabilistic sensitivity analysis) is used in economic models to explore uncertainty in several parameters simultaneously and is done using Monte Carlo simulation. Model inputs are defined as a distribution of possible values. In each iteration, model inputs are obtained by randomly sampling from each distribution, and a single estimate of cost and effectiveness is generated. This process is repeated many times (e.g., 10,000 times) to estimate the number of times (i.e., the probability) that the health care intervention of interest is cost-effective.

Quality-adjusted life-year (QALY): The quality-adjusted life-year (QALY) is a generic health outcome measure commonly used in cost–utility analyses to reflect the quantity and quality of life-years lived. The life-years lived are adjusted for quality of life using individual or societal preferences (i.e., utility values) for being in a particular health state. One year of perfect health is represented by 1 quality-adjusted life-year.

Reference case: The reference case is a preferred set of methods and principles that provide the guidelines for economic evaluations. Its purpose is to standardize the approach of conducting and reporting economic evaluations, so that results can be compared across studies.

Scenario analysis: A scenario analysis is used to explore uncertainty in the results of an economic evaluation. It is done by observing the potential impact of different scenarios on the cost-effectiveness of a health care intervention. Scenario analyses include varying structural assumptions from the reference case.

Sensitivity analysis: Every economic evaluation contains some degree of uncertainty, and results can vary depending on the values taken by key parameters and the assumptions made. Sensitivity analysis allows these factors to be varied and shows the impact of these variations on the results of the evaluation. There are various types of sensitivity analysis, including deterministic, probabilistic, and scenario.

Short-Form–Six Dimensions (SF-6D): The SF-6D is a generic health-related quality-of-life classification system widely used in clinical studies. In economic evaluations, it is used as an indirect method of obtaining health state preferences (i.e., utility values). The classification system consists of 6 attributes (physical functioning, role limitations, social functioning, pain, mental health, and vitality), each associated with 4 to 6 levels, thus producing a total of 18,000 possible unique health states. A scoring table is used to convert SF-6D scores to health state values.

Societal perspective: The perspective adopted in an economic evaluation determines the types of costs and health benefits to include. The societal perspective reflects the broader economy and is the aggregation of all perspectives (e.g., health care payer and patient perspectives). It considers the full effect of a health condition on society, including all costs (regardless of who pays) and all benefits (regardless of who benefits).

Time horizon: In economic evaluations, the time horizon is the time frame over which costs and benefits are examined and calculated. The relevant time horizon is chosen based on the nature of the disease and health care intervention being assessed, as well as the purpose of the analysis. For instance, a

lifetime horizon would be chosen to capture the long-term health and cost consequences over a patient's lifetime.

Uptake rate: In instances where 2 technologies are being compared, the uptake rate is the rate at which a new technology is adopted. When a new technology is adopted, it may be used in addition to an existing technology, or it may replace an existing technology.

Utility: A utility is a value that represents a person's preference for various health states. Typically, utility values are anchored at 0 (death) and 1 (perfect health). In some scoring systems, a negative utility value indicates a state of health valued as being worse than death. Utility values can be aggregated over time to derive quality-adjusted life-years, a common outcome measure in economic evaluations.

Willingness-to-pay value: A willingness-to-pay value is the monetary value a health care consumer is willing to pay for added health benefits. When conducting a cost–utility analysis, the willingness-to-pay value represents the cost a consumer is willing to pay for an additional quality-adjusted life-year. If the incremental cost-effectiveness ratio is less than the willingness-to-pay value, the health care intervention of interest is considered cost-effective. If the incremental cost-effectiveness ratio is more than the willingness-to-pay value, the intervention is considered not to be cost-effective.

Appendices

Appendix 1: Literature Search Strategies

Clinical Evidence Search

Search date: May 25, 2023

Databases searched for 2021 NICE Update: Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and EBSCO CINAHL

Databases searched for supplemental search (starts at Line 217): Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, NHS Economic Evaluation Database, and EBSCO CINAHL

Database segments: EBM Reviews - Cochrane Central Register of Controlled Trials <April 2023>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to May 23, 2023>, Embase <1980 to 2023 Week 20>, Ovid MEDLINE(R) ALL <1946 to May 24, 2023>

Search Strategy:

- 1 Pelvic Floor/ or Pelvic Floor Disorders/ or exp *Urinary Incontinence/ or *Urinary Bladder, Overactive/ or exp *Pelvic Organ Prolapse/ or *Rectocele/ or *Fecal Incontinence/ or Urinary Retention/ or Fecal Impaction/ or Vaginismus/ (140306)
- 2 (pelvi* adj (floor* or diaphragm*) adj3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).ti,ab,kf. (13796)
- 3 (pelvi* adj (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).ti,ab,kf. (2603)
- 4 ((stress* or mix* or urg* or urin*) adj5 incontinen*).ti. (42359)
- 5 ((bladder* or detrusor*) adj5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*).ti. (18649)
- 6 (urgency adj2 frequency).ti. (228)
- 7 ((urin* or bladder*) adj2 (urg* or frequen*)).ti. (2354)
- 8 (SUI or OAB).ti. (2132)
- 9 (pelvic* adj3 organ* adj3 prolaps*).ti. (9009)
- 10 (urinary adj3 bladder adj3 prolaps*).ti. (39)
- 11 ((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) adj3 prolaps*).ti. (21929)
- 12 (splanchnoptos* or visceroptos*).ti. (55)
- 13 (hernia* adj3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)).ti. (1189)
- 14 (urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*).ti. (2638)
- 15 ((f?ecal or f?eces or f?ecally or anal or anally or stool\$1 or bowel or double or def?ecat*) adj5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti. (11147)
- 16 (urin* adj3 (retention* or retain*)).ti,ab,kf. (37024)
- 17 (voiding adj (disorder* or dysfunction* or problem*)).ti,ab,kf. (9816)
- 18 (empty* adj disorder* adj3 (bowel* or bladder* or vesical* or stool*)).ti,ab,kf. (74)

- 19 ((urogeni* or anorec* or ano-rec*) adj3 dysfunction*).ti,ab,kf. (1303)
- 20 ((difficult* or delay* or irregular* or infrequen* or pain*) adj3 (def?ecat* or stool* or f?eces or bowel movement*).ti,ab,kf. (8906)
- 21 (obstruct* adj3 def?ecat*).ti,ab,kf. (2975)
- 22 ((def?ecat* or evacuat*) adj3 (disorder* or dysfunction*).ti,ab,kf. (3772)
- 23 outlet* dysfunction* constipa*.ti,ab,kf. (12)
- 24 (dys?ynerg* adj def?ecat*).ti,ab,kf. (865)
- 25 (pelvi* adj3 dyskines*).ti,ab,kf. (21)
- 26 pelvi* outlet* obstruct*.ti,ab,kf. (66)
- 27 anismus*.ti,ab,kf. (630)
- 28 puborectal* contract*.ti,ab,kf. (156)
- 29 ((rectal or rectum) adj3 urge*).ti,ab,kf. (668)
- 30 (female adj sex* adj (dysfunct* or satisf* or problem* or symptom* or arouse* or activit* or disorder*).ti,ab,kf. (6167)
- 31 (obstruct* adj3 intercourse).ti,ab,kf. (13)
- 32 (vagin* adj3 laxity*).ti,ab,kf. (429)
- 33 (vagin* adj wind).ti,ab,kf. (24)
- 34 vaginismus*.ti,ab,kf. (1365)
- 35 (vagin* adj penetrat* adj disorder*).ti,ab,kf. (9)
- 36 or/1-35 (224490)
- 37 exp Exercise Therapy/ or Physical Therapy Modalities/ or Electric Stimulation/ or *Electric Stimulation Therapy/ or Transcutaneous Electric Nerve Stimulation/ or *Magnetics/ or Magnetic Field Therapy/ or Biofeedback, Psychology/ or Resistance Training/ (570937)
- 38 (((pelvi* adj (floor* or muscl*) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*).ti,ab,kf. (9739)
- 39 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).ti,ab,kf. (231)
- 40 (pelvi* adj floor* adj (physiotherap* or physical therap*).ti,ab,kf. (1289)
- 41 (PFMT or PFME or PFPT).ti,ab,kf. (2664)
- 42 (kegel* or kegal* or knack*).ti,ab,kf. (1698)
- 43 (physiotherap* or physical therap*).ti. (45668)
- 44 physiotherapy-led.ti,ab,kf. (528)
- 45 (vagin* adj3 (cone or cones or ball or balls)).ti,ab,kf. (374)
- 46 (weight adj (cone or cones)).ti,ab,kf. (20)
- 47 (pelvi* adj floor* adj2 (cone or cones)).ti,ab,kf. (27)
- 48 ((cone or cones) adj5 (continen* or incontinen*).ti. (53)
- 49 ((electr* adj3 stimulat*) or electrostimulat* or electro-stimulat*).ti,ab,kf. (199502)
- 50 ((transcutaneous* or percutaneous* or neuromusc* or posterior* or anterior* or tibia* or perine* or intravagin* or intra-vagin*) adj4 stimulat*).ti,ab,kf. (39439)
- 51 ((magnet* or electro-magnet* or electromagnet*) adj (stimulation* or therap* or treatment* or innervation*).ti,ab,kf. (59641)
- 52 ((magnet* or electro-magnet* or electromagnet*) adj (nerve* or energ* or pelvi* floor or pelvi* muscl*) adj (stimulation* or therap* or treatment*).ti,ab,kf. (141)
- 53 (interferential* adj3 (current or currents or therap* or treatment*).ti,ab,kf. (1266)
- 54 hifem*.ti,ab,kf. (156)
- 55 (biofeedback* or bio-feedback*).mp. (28710)
- 56 ((digital* or manual*) adj3 (feedback* or palpat* or assess* or contract*).ti,ab,kf. (18602)
- 57 (pressure* adj3 perin?ometr*).ti,ab,kf. (43)
- 58 ((strength* or resistan*) adj3 (training or exercise* or physiotherap*).ti,ab,kf. (92767)

59 (manual adj3 therap*).ti,ab,kf. (12796)

60 (myofascia* adj3 (release* or therap* or technique*).ti,ab,kf. (2744)

61 or/37-60 (835741)

62 36 and 61 (23607)

63 62 use medall (7829)

64 (Systematic Reviews or Meta Analysis).pt. (181162)

65 Systematic Review/ or Systematic Reviews as Topic/ or Meta-Analysis/ or exp Meta-Analysis as Topic/ or exp Technology Assessment, Biomedical/ (986884)

66 ((systematic* or methodologic*) adj3 (review* or overview*).ti,ab,kf. (723006)

67 (meta analy* or metaanaly* or met analy* or metanaly* or meta review* or metareview* or health technolog* assess* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).ti,ab,kf. (675956)

68 (evidence adj2 (review* or overview* or synthes#s)).ti,ab,kf. (102747)

69 (review of reviews or overview of reviews).ti,ab,kf. (2538)

70 umbrella review*.ti,ab,kf. (3026)

71 GRADE Approach/ (3056)

72 ((pool* adj3 analy*) or published studies or published literature or hand search* or handsearch* or manual search* or ((database* or systematic*) adj2 search*) or reference list* or bibliograph* or relevant journals or data synthes* or data extraction* or data abstraction*).ti,ab,kf. (652937)

73 (medline or pubmed or medlars or embase or cinahl or web of science or ovid or ebSCO* or scopus).ab. (758786)

74 cochrane.ti,ab,kf. (321459)

75 (meta regress* or metaregress*).ti,ab,kf. (33154)

76 (((integrative or collaborative or quantitative) adj3 (review* or overview* or synthes*)) or (research adj3 overview*).ti,ab,kf. (39696)

77 (cochrane or (health adj2 technology assessment) or evidence report or systematic review*).jw. (77585)

78 ((comparative adj3 (efficacy or effectiveness)) or relative effectiveness or ((indirect or indirect treatment or mixed-treatment) adj comparison*).ti,ab,kf. (67109)

79 or/64-78 (1879536)

80 63 and 79 (785)

81 Clinical Trials as Topic/ (335132)

82 controlled clinical trials as topic/ (18366)

83 exp Randomized Controlled Trials as Topic/ (466676)

84 controlled clinical trial.pt. (95308)

85 randomized controlled trial.pt. (593127)

86 Pragmatic Clinical Trial.pt. (2221)

87 Random Allocation/ (225277)

88 Single-Blind Method/ (106839)

89 Double-Blind Method/ (512170)

90 Placebos/ (393743)

91 trial.ti. (1082688)

92 (random* or sham or placebo* or RCT*1).ti,ab,kf. (5038838)

93 ((singl* or doubl*) adj (blind* or dumm* or mask*).ti,ab,kf. (782262)

94 ((tripl* or trebl*) adj (blind* or dumm* or mask*).ti,ab,kf. (6228)

95 or/81-94 (6080290)

96 exp Animals/ not Humans/ (16326015)

97 95 not 96 (4920792)

98 63 and 97 (1989)

99 80 or 98 (2332)

100 exp Animals/ not Humans/ (16326015)

101 99 not 100 (2332)

102 Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt. (6385629)

103 101 not 102 (2240)

104 limit 103 to english language [Limit not valid in CDSR; records were retained] (2101)

105 limit 104 to yr="2021 -Current" (479)

106 62 use cctr,coch (3024)

107 ((Letter not (Letter and Randomized Controlled Trial)) or Conference proceeding or Editorial or Comment or Trial registry record).pt. (5003048)

108 106 not 107 (1568)

109 limit 108 to yr="2021 -Current" (221)

110 pelvis floor/ or pelvic floor disorder/ or exp *urine incontinence/ or *overactive bladder/ or *bladder instability/ or exp *pelvic organ prolapse/ or *rectocele/ or *feces incontinence/ or urine retention/ or defecation disorder/ or Feces Impaction/ or female sexual dysfunction/ or vaginism/ (133954)

111 (pelvi* adj (floor* or diaphragm*) adj3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*).tw,kw,kf. (13965)

112 (pelvi* adj (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*).tw,kw,kf. (3857)

113 ((stress* or mix* or urg* or urin*) adj5 incontinen*).ti. (42359)

114 ((bladder* or detrusor*) adj5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*).ti. (18649)

115 (urgency adj2 frequency).ti. (228)

116 ((urin* or bladder*) adj2 (urg* or frequen*).ti. (2354)

117 (SUI or OAB).ti. (2132)

118 (pelvic* adj3 organ* adj3 prolaps*).ti. (9009)

119 (urinary adj3 bladder adj3 prolaps*).ti. (39)

120 ((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) adj3 prolaps*).ti. (21929)

121 (splanchnoptos* or visceroptos*).ti. (55)

122 (hernia* adj3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*).ti. (1189)

123 (urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*).ti. (2638)

124 ((f?ecal or f?eces or f?ecally or anal or anally or stool\$1 or bowel or double or def?ecat*) adj5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti. (11147)

125 (urin* adj3 (retention* or retain*).tw,kw,kf. (37883)

126 (voiding adj (disorder* or dysfunction* or problem*).tw,kw,kf. (9872)

127 (empty* adj disorder* adj3 (bowel* or bladder* or vesical* or stool*).tw,kw,kf. (74)

128 ((urogeni* or anorec* or ano-rec*) adj3 dysfunction*).tw,kw,kf. (1311)

129 ((difficult* or delay* or irregular* or infrequen* or pain*) adj3 (def?ecat* or stool* or f?eces or bowel movement*).tw,kw,kf. (9074)

- 130 (obstruct* adj3 def?ecat*).tw,kw,kf. (2984)
- 131 ((def?ecat* or evacuat*) adj3 (disorder* or dysfunction*)).tw,kw,kf. (3857)
- 132 outlet* dysfunction* constipa*.tw,kw,kf. (12)
- 133 (dys?ynerg* adj def?ecat*).tw,kw,kf. (868)
- 134 (pelvi* adj3 dyskines*).tw,kw,kf. (21)
- 135 pelvi* outlet* obstruct*.tw,kw,kf. (67)
- 136 anismus*.tw,kw,kf. (634)
- 137 puborectal* contract*.tw,kw,kf. (157)
- 138 ((rectal or rectum) adj3 urge*).tw,kw,kf. (673)
- 139 (female adj sex* adj (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*)).tw,kw,kf. (6258)
- 140 (obstruct* adj3 intercourse).tw,kw,kf. (13)
- 141 (vagin* adj3 laxity*).tw,kw,kf. (431)
- 142 (vagin* adj wind).tw,kw,kf. (25)
- 143 vaginismus*.tw,kw,kf. (1444)
- 144 (vagin* adj penetrat* adj disorder*).tw,kw,kf. (9)
- 145 or/110-144 (223064)
- 146 *physiotherapy/ or pelvic floor muscle training/ or kinesiotherapy/ or *muscle exercise/ or vaginal cone/ or vagina cone/ or weighted vaginal cone/ or electrostimulation/ or electrotherapy/ or transcutaneous nerve stimulation/ or magnetic stimulation/ or magnetotherapy/ or extracorporeal magnetic innervation therapy/ or feedback system/ or biofeedback/ or perineometry/ or resistance training/ (321608)
- 147 (((pelvi* adj (floor* or muscl*)) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*)).tw,kw,kf,dv. (9914)
- 148 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).tw,kw,kf,dv. (266)
- 149 (pelvi* adj floor* adj (physiotherap* or physical therap*)).tw,kw,kf,dv. (1314)
- 150 (PFMT or PFME or PFPT).tw,kw,kf,dv. (2686)
- 151 (kegel* or kegal* or knack*).tw,kw,kf,dv. (1765)
- 152 (physiotherap* or physical therap*).ti. (45668)
- 153 physiotherapy-led.tw,kw,kf,dv. (533)
- 154 (vagin* adj3 (cone or cones or ball or balls)).tw,kw,kf,dv. (388)
- 155 (weight adj (cone or cones)).tw,kw,kf,dv. (20)
- 156 (pelvi* adj floor* adj2 (cone or cones)).tw,kw,kf,dv. (27)
- 157 ((cone or cones) adj5 (continen* or incontinen*)).ti. (53)
- 158 ((electr* adj3 stimulat*) or electrostimulat* or electro-stimulat*).tw,kw,kf,dv. (201168)
- 159 ((transcutaneous* or percutaneous* or neuromusc* or posterior* or anterior* or tibia* or perine* or intravagin* or intra-vagin*) adj4 stimulat*).tw,kw,kf,dv. (40265)
- 160 ((magnet* or electro-magnet* or electromagnet*) adj (stimulation* or therap* or treatment* or innervation*)).tw,kw,kf,dv. (61689)
- 161 ((magnet* or electro-magnet* or electromagnet*) adj (nerve* or energ* or pelvi* floor or pelvi* muscl*) adj (stimulation* or therap* or treatment*)).tw,kw,kf,dv. (145)
- 162 (interferential* adj3 (current or currents or therap* or treatment*)).tw,kw,kf,dv. (1304)
- 163 hifem*.tw,kw,kf,dv. (156)
- 164 (biofeedback* or bio-feedback*).mp. (28710)
- 165 ((digital* or manual*) adj3 (feedback* or palpat* or assess* or contract*)).tw,kw,kf,dv. (18924)
- 166 (pressure* adj3 perin?ometr*).tw,kw,kf,dv. (43)
- 167 ((strength* or resistan*) adj3 (training or exercise* or physiotherap*)).tw,kw,kf,dv. (95564)
- 168 (manual adj3 therap*).tw,kw,kf,dv. (13096)

169 (myofascia* adj3 (release* or therap* or technique*)).tw,kw,kf,dv. (2950)

170 or/146-169 (652044)

171 145 and 170 (21541)

172 171 use emez (12649)

173 Systematic review/ or "systematic review (topic)"/ or exp Meta Analysis/ or "Meta Analysis (Topic)"/ or Biomedical Technology Assessment/ (958329)

Annotation: Added Systematic review/ or "systematic review (topic)"/ for thoroughness, but these may add many results. Will monitor

174 (meta analy* or metaanaly* or health technolog* assess* or systematic review*).hw. (973260)

175 ((systematic* or methodologic*) adj3 (review* or overview*)).tw,kw,kf. (737032)

176 (meta analy* or metaanaly* or met analy* or metanaly* or meta review* or metareview* or health technolog* assess* or HTA or HTAs or (technolog* adj (assessment* or overview* or appraisal*))).tw,kw,kf. (689437)

177 (evidence adj2 (review* or overview* or synthes#s)).tw,kw,kf. (105072)

178 (review of reviews or overview of reviews).tw,kw,kf. (2754)

179 umbrella review*.tw,kw,kf. (3056)

180 ((pool* adj3 analy*) or published studies or published literature or hand search* or handsearch* or manual search* or ((database* or systematic*) adj2 search*) or reference list* or bibliograph* or relevant journals or data synthes* or data extraction* or data abstraction*).tw,kw,kf. (662629)

181 (medline or pubmed or medlars or embase or cinahl or web of science or ovid or ebSCO* or scopus).ab. (758786)

182 cochrane.tw,kw,kf. (325090)

183 (meta regress* or metaregress*).tw,kw,kf. (34133)

184 (((integrative or collaborative or quantitative) adj3 (review* or overview* or synthes*)) or (research adj3 overview*)).tw,kw,kf. (40785)

185 (cochrane or (health adj2 technology assessment) or evidence report or systematic review*).jw. (77585)

186 ((comparative adj3 (efficacy or effectiveness)) or relative effectiveness or ((indirect or indirect treatment or mixed-treatment) adj comparison*)).tw,kw,kf. (103136)

187 or/173-186 (1921335)

188 172 and 187 (1306)

189 "clinical trial (topic)"/ (128790)

190 "controlled clinical trial (topic)"/ (13964)

191 "randomized controlled trial (topic)"/ (262003)

192 randomization/ (210146)

193 Single Blind Procedure/ (54088)

194 Double Blind Procedure/ (215882)

195 placebo/ (389015)

196 trial.ti. (1082688)

197 (random* or sham or placebo* or RCT*1).tw,kw,kf. (5102101)

198 ((singl* or doubl*) adj (blind* or dumm* or mask*)).tw,kw,kf. (816929)

199 ((tripl* or trebl*) adj (blind* or dumm* or mask*)).tw,kw,kf. (6868)

200 or/189-199 (5786930)

201 (exp animal/ or nonhuman/) not exp human/ (11883723)

202 200 not 201 (5211104)

203 172 and 202 (3401)

204 188 or 203 (3921)

205 (exp animal/ or nonhuman/) not exp human/ (11883723)

206 204 not 205 (3915)

207 Case Report/ or Comment/ or Editorial/ or (letter.pt. not (letter.pt. and randomized controlled trial/)) or conference abstract.pt. or conference review.pt. (11191209)

208 206 not 207 (2856)

209 limit 208 to english language [Limit not valid in CDSR; records were retained] (2688)

210 limit 208 to yr="2021 -Current" (573)

211 105 or 109 or 210 (1273)

212 211 use medall (479)

213 211 use emez (573)

214 211 use cctr (221)

215 211 use coch (0)

216 remove duplicates from 211 (698)

[SUPPLEMENTAL SEARCH to 2021 NICE SEARCH]

Database segments: EBM Reviews - Cochrane Central Register of Controlled Trials <April 2023>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to May 23, 2023>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2023 Week 20>, Ovid MEDLINE(R) ALL <1946 to May 24, 2023>

217 exp Prostatectomy/ or (prostatectom* or prostate* surger* or (prostat* adj2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesction*)) or turp or turp* or tuvp or vlap).ti,ab,kf. (141864)

218 exp Exercise Therapy/ or Physical Therapy Modalities/ (306092)

219 (((pelvi* adj (floor* or muscl*)) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*).ti,ab,kf. (9739)

220 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).ti,ab,kf. (231)

221 (pelvi* adj floor* adj (physiotherap* or physical therap*).ti,ab,kf. (1289)

222 (PFMT or PFME or PFPT).ti,ab,kf. (2664)

223 (kegel* or kegal* or knack*).ti,ab,kf. (1698)

224 (physiotherap* or physical therap*).ti. (45668)

225 physiotherapy-led.ti,ab,kf. (528)

226 or/218-225 (327390)

227 217 and 226 (1523)

228 36 and 226 (13805)

229 ((women not men) or (female not male)).tw. (3337608)

230 228 not 229 (5931)

231 228 and Male/ (2613)

232 transgender persons/ or sex reassignment surgery/ or sex reassignment procedures/ or health services for transgender persons/ (190007)

233 (transgender* or transsexual* or "gender identity" or "male-to-female" or "female-to-male" or "sex reassignment" or "gender dysphoria" or "trans men" or cross gender* or "gender reassignment" or "trans people" or "gender change" or "gender transition" or "trans female" or "trans women").ti,ab. (463571)

234 (or/232-233) and 228 (112)

235 227 or 230 or 231 or 234 (6830)

236 235 use medall (1790)

237 79 and 236 (236)

238 97 and 236 (507)

239 237 or 238 (609)

240 exp Animals/ not Humans/ (16326015)

241 239 not 240 (609)
 242 Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt. (6385629)
 243 241 not 242 (569)
 244 limit 243 to english language [Limit not valid in CDSR; records were retained] (525)
 245 limit 244 to yr="1980 -Current" (525)
 246 235 use cctr,coch (810)
 247 ((Letter not (Letter and Randomized Controlled Trial)) or Conference proceeding or Editorial or Comment or Trial registry record).pt. (5003048)
 248 246 not 247 (423)
 249 limit 248 to yr="1980 -Current" (420)
 250 235 use cleed (3)
 251 exp Prostatectomy/ or (prostatectom* or prostate* surger* or (prostat* adj2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesction*)) or turp or turp* or tuvp or vlap).tw,kw,kf. (142327)
 252 physiotherapy/ or pelvic floor muscle training/ or kinesiotherapy/ or *muscle exercise/ (140825)
 253 (((pelvi* adj (floor* or muscl*)) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*).tw,kw,kf,dv. (9914)
 254 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).tw,kw,kf,dv. (266)
 255 (pelvi* adj floor* adj (physiotherap* or physical therap*).tw,kw,kf,dv. (1314)
 256 (PFMT or PFME or PFPT).tw,kw,kf,dv. (2686)
 257 (kegel* or kegal* or knack*).tw,kw,kf,dv. (1765)
 258 (physiotherap* or physical therap*).ti. (45668)
 259 physiotherapy-led.tw,kw,kf,dv. (533)
 260 or/252-259 (176734)
 261 251 and 260 (1434)
 262 145 and 260 (12562)
 263 ((women not men) or (female not male)).tw. (3337608)
 264 262 not 263 (5382)
 265 262 and Male/ (2266)
 266 exp transgender/ or sex reassignment/ (20624)
 267 (transgender* or transsexual* or gender identity or sex reassignment or gender dysphoria or cross gender* or gender reassignment or trans people or gender change or gender transition).ti,ab. (38816)
 268 (or/266-267) and 262 (25)
 269 261 or 264 or 265 or 268 (6292)
 270 269 use emez (4367)
 271 187 and 270 (523)
 272 202 and 270 (1078)
 273 271 or 272 (1313)
 274 (exp animal/ or nonhuman/) not exp human/ (11883723)
 275 273 not 274 (1312)
 276 Case Report/ or Comment/ or Editorial/ or (letter.pt. not (letter.pt. and randomized controlled trial/)) or conference abstract.pt. or conference review.pt. (11191209)
 277 275 not 276 (979)
 278 limit 277 to english language [Limit not valid in CDSR; records were retained] (930)
 279 limit 278 to yr="1980 -Current" (929)
 280 245 or 249 or 250 or 279 (1877)

281 280 use medall (525)
282 280 use emez (929)
283 280 use cctr (409)
284 280 use coch (11)
285 280 use cleed (3)

CINAHL

Query Results

S1 MH("Pelvic Floor Muscles" OR "Pelvic Floor Disorders" OR "Urinary Retention" OR "Feces, Impacted" OR "Vaginismus") OR MM("Urinary Incontinence+" OR "Pelvic Organ Prolapse+" OR "Rectocele" OR "Fecal Incontinence") 17,054
S2 (pelvi* N1 (floor* or diaphragm*) N3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)) 1,830
S3 (pelvi* N1 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)) 2,836
S4 TI((stress* or mix* or urg* or urin*) N5 incontinen*) 5,551
S5 TI((bladder* or detrusor*) N5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*)) 1,657
S6 TI(urgency N2 frequency) 21
S7 TI((urin* or bladder*) N2 (urg* or frequen*)) 302
S8 TI(SUI or OAB) 444
S9 TI(pelvic* N3 organ* N3 prolaps*) 1,258
S10 TI(urinary N3 bladder N3 prolaps*) 4
S11 TI((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) N3 prolaps*) 2,260
S12 TI(splanchnoptos* or visceroptos*) 0
S13 TI(hernia* N3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)) 124
S14 TI(urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocoele* or proctocoele* or proctocoele* or rectocoele* or rectocoele* or cystocoele* or cystocoele* or rectoenterocoele* or rectoenterocoele* or cystourethrocele* or cystourethrocoele*) 161
S15 TI((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat* or defaecat*) N5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti 0
S16 (urin* N3 (retention* or retain*)) 3,230
S17 (voiding N1 (disorder* or dysfunction* or problem*)) 635
S18 (empty* N1 disorder* N3 (bowel* or bladder* or vesical* or stool*)) 7
S19 ((urogeni* or anorec* or ano-rec*) N3 dysfunction*) 108
S20 ((difficult* or delay* or irregular* or infrequen* or pain*) N3 (defecat* or defaecat* or stool* or faeces or feces or bowel movement*)) 809
S21 (obstruct* N3 (defecat* or defaecat*)) 130
S22 ((defecat* or defaecat* or evacuat*) N3 (disorder* or dysfunction*)) 245
S23 outlet* dysfunction* constipa* 3
S24 (dyssynerg* N1 (defecat* or defaecat*)) 42
S25 pelvi* N3 dyskines* 0
S26 pelvi* outlet* obstruct* 2
S27 anismus* 22

S28 puborectal* contract* 5
 S29 ((rectal or rectum) N3 urge*) 56
 S30 (female N1 sex* N1 (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*)) 3,537
 S31 (obstruct* N3 intercourse) 0
 S32 (vagin* N3 laxity*) 38
 S33 (vagin* N1 wind) 4
 S34 vaginismus* 171
 S35 (vagin* N1 penetrat* N1 disorder*) 2
 S36 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 28,104
 S37 MH ("Muscle Strengthening" OR "Kegel Exercises" OR "Physical Therapy+") 159,148
 S38 (((pelvi* N1 (floor* or muscl*)) or PFM*) N3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*)) 1,567
 S39 (pelvi* N1 floor* N1 muscl* N1 (physiotherap* or therap* or treatment)) 74
 S40 (pelvi* N1 floor* N1 (physiotherap* or physical therap*)) 159
 S41 (PFMT or PFME or PFPT) 263
 S42 (kegel* or kegal* or knack*) 2,120
 S43 TI(physiotherap* or physical therap*) 21,796
 S44 physiotherapy-led 131
 S45 S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 170,127
 S46 S36 AND S45 3,682
 S47 (PT "Meta Analysis") or (PT "Systematic Review") 158,315
 S48 (MH "Systematic Review") OR (MH "Meta Analysis") 152,071
 S49 ((systematic* or methodologic*) N3 (review* or overview*)) 198,335
 S50 (meta analy* or metaanaly* or met analy* or metanaly* or meta review* or metareview* or health technolog* assess* or HTA or HTAs or (technolog* N1 (assessment* or overview* or appraisal*))) 125,638
 S51 (evidence N2 (review* or overview* or synthes#s)) 27,960
 S52 ((review or overview) N2 reviews) 9,101
 S53 umbrella review* 666
 S54 ((pool* N3 analy*) or published studies or published literature or hand search* or handsearch* or manual search* or ((database* or systematic*) N2 search*) or reference list* or bibliograph* or relevant journals or data synthes* or data extraction* or data abstraction*) 127,032
 S55 AB(medline or pubmed or medlars or embase or cinahl or web of science or ovid or ebsco* or scopus) 122,641
 S56 cochrane 70,428
 S57 (meta regress* or metaregress*) 5,118
 S58 (((integrative or collaborative or quantitative) N3 (review* or overview* or synthes*)) or (research N3 overview*)) 13,468
 S59 SO(cochrane or (health N2 technology assessment) or evidence report or systematic review*) 12,199
 S60 ((comparative N3 (efficacy or effectiveness)) or relative effectiveness or ((indirect or indirect treatment or mixed-treatment) N1 comparison*)) 9,981
 S61 S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 353,929
 S62 S46 AND S61 387

S63 (MH "Randomized Controlled Trials+") 136,787
 S64 (PT "randomized controlled trial") 150,533
 S65 (MH "Random Assignment") 78,696
 S66 (MH "Single-Blind Studies") 15,908
 S67 (MH "Double-Blind Studies") 54,118
 S68 (MH "Placebos") 13,998
 S69 TI trial 178,975
 S70 (random* or sham or placebo* or RCT or RCTs) 539,832
 S71 ((singl* or doubl*) N1 (blind* or dumm* or mask*)) 87,453
 S72 ((tripl* or trebl*) N1 (blind* or dumm* or mask*)) 760
 S73 S63 OR S64 OR S65 OR S66 OR S67 OR S68 OR S69 OR S70 OR S71 OR S72 601,156
 S74 (MH "Animals+") not (MH "Animals+" and MH "Human") 95,540
 S75 S73 not S74 595,328
 S76 S46 AND S75 738
 S77 S62 OR S76 972
 S78 (MH "Animals+") not (MH "Animals+" and MH "Human") 95,540
 S79 S77 NOT S78 972
 S80 PT (Case Study or Commentary or Editorial or Letter or Proceedings) 1,347,819
 S81 S79 NOT S80 905
 S82 Limiters - Published Date: 20210101-20231231 153
 S83 Limiters - English Language 139
 S84 (MH "Prostatectomy+") 751
 S85 (prostatectom* or prostate* surger* or (prostat* N2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesction*)) or turp or turp* or tuvp or vlap) 1,408
 S86 S84 OR S85 1,408
 S87 S45 AND S86 44
 S88 S61 AND S87 12
 S89 S75 AND S87 13
 S90 S88 OR S89 21
 S91 S90 NOT S78 21
 S92 S91 NOT S80 20

Economic Evidence Search

Search date: June 6, 2023

Databases searched: Ovid MEDLINE, Embase, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, NHS Economic Evaluation Database, and CINAHL

Database segments: EBM Reviews - Cochrane Central Register of Controlled Trials <May 2023>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to May 31, 2023>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2023 Week 22>, Ovid MEDLINE(R) ALL <1946 to June 05, 2023>

Search Strategy:

1 Pelvic Floor/ or Pelvic Floor Disorders/ or exp *Urinary Incontinence/ or *Urinary Bladder, Overactive/ or exp *Pelvic Organ Prolapse/ or *Rectocele/ or *Fecal Incontinence/ or Urinary Retention/ or Fecal Impaction/ or Vaginismus/ (140685)

- 2 (pelvi* adj (floor* or diaphragm*) adj3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).ti,ab,kf. (13852)
- 3 (pelvi* adj (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).ti,ab,kf. (2610)
- 4 ((stress* or mix* or urg* or urin*) adj5 incontinen*).ti. (42451)
- 5 ((bladder* or detrusor*) adj5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*).ti. (18699)
- 6 (urgency adj2 frequency).ti. (228)
- 7 ((urin* or bladder*) adj2 (urg* or frequen*)).ti. (2368)
- 8 (SUI or OAB).ti. (2142)
- 9 (pelvic* adj3 organ* adj3 prolaps*).ti. (9035)
- 10 (urinary adj3 bladder adj3 prolaps*).ti. (39)
- 11 ((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) adj3 prolaps*).ti. (21981)
- 12 (splanchnoptos* or visceroptos*).ti. (55)
- 13 (hernia* adj3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)).ti. (1190)
- 14 (urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*).ti. (2642)
- 15 ((f?ecal or f?eces or f?ecally or anal or anally or stool\$1 or bowel or double or def?ecat*) adj5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti. (11174)
- 16 (urin* adj3 (retention* or retain*)).ti,ab,kf. (37117)
- 17 (voiding adj (disorder* or dysfunction* or problem*)).ti,ab,kf. (9824)
- 18 (empty* adj disorder* adj3 (bowel* or bladder* or vesical* or stool*)).ti,ab,kf. (75)
- 19 ((urogeni* or anorec* or ano-rec*) adj3 dysfunction*).ti,ab,kf. (1308)
- 20 ((difficult* or delay* or irregular* or infrequen* or pain*) adj3 (def?ecat* or stool* or f?eces or bowel movement*)).ti,ab,kf. (8945)
- 21 (obstruct* adj3 def?ecat*).ti,ab,kf. (2977)
- 22 ((def?ecat* or evacuat*) adj3 (disorder* or dysfunction*)).ti,ab,kf. (3781)
- 23 outlet* dysfunction* constipa*.ti,ab,kf. (12)
- 24 (dys?ynerg* adj def?ecat*).ti,ab,kf. (867)
- 25 (pelvi* adj3 dyskines*).ti,ab,kf. (21)
- 26 pelvi* outlet* obstruct*.ti,ab,kf. (66)
- 27 anismus*.ti,ab,kf. (632)
- 28 puborectal* contract*.ti,ab,kf. (156)
- 29 ((rectal or rectum) adj3 urge*).ti,ab,kf. (668)
- 30 (female adj sex* adj (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*)).ti,ab,kf. (6197)
- 31 (obstruct* adj3 intercourse).ti,ab,kf. (13)
- 32 (vagin* adj3 laxity*).ti,ab,kf. (432)
- 33 (vagin* adj wind).ti,ab,kf. (25)
- 34 vaginismus*.ti,ab,kf. (1369)
- 35 (vagin* adj penetrat* adj disorder*).ti,ab,kf. (9)
- 36 or/1-35 (225053)

37 exp Exercise Therapy/ or Physical Therapy Modalities/ or Electric Stimulation/ or *Electric Stimulation Therapy/ or Transcutaneous Electric Nerve Stimulation/ or *Magnetics/ or Magnetic Field Therapy/ or Biofeedback, Psychology/ or Resistance Training/ (572044)

38 (((pelvi* adj (floor* or muscl*)) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*).ti,ab,kf. (9778)

39 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).ti,ab,kf. (232)

40 (pelvi* adj floor* adj (physiotherap* or physical therap*).ti,ab,kf. (1295)

41 (PFMT or PFME or PFPT).ti,ab,kf. (2681)

42 (kegel* or kegal* or knack*).ti,ab,kf. (1706)

43 (physiotherap* or physical therap*).ti. (45836)

44 physiotherapy-led.ti,ab,kf. (529)

45 (vagin* adj3 (cone or cones or ball or balls)).ti,ab,kf. (375)

46 (weight adj (cone or cones)).ti,ab,kf. (20)

47 (pelvi* adj floor* adj2 (cone or cones)).ti,ab,kf. (27)

48 ((cone or cones) adj5 (continen* or incontinen*).ti. (53)

49 ((electr* adj3 stimulat*) or electrostimulat* or electro-stimulat*).ti,ab,kf. (199933)

50 ((transcutaneous* or percutaneous* or neuromusc* or posterior* or anterior* or tibia* or perine* or intravagin* or intra-vagin*) adj4 stimulat*).ti,ab,kf. (39607)

51 ((magnet* or electro-magnet* or electromagnet*) adj (stimulation* or therap* or treatment* or innervation*).ti,ab,kf. (59907)

52 ((magnet* or electro-magnet* or electromagnet*) adj (nerve* or energ* or pelvi* floor or pelvi* muscl*) adj (stimulation* or therap* or treatment*).ti,ab,kf. (141)

53 (interferential* adj3 (current or currents or therap* or treatment*).ti,ab,kf. (1269)

54 hifem*.ti,ab,kf. (156)

55 (biofeedback* or bio-feedback*).mp. (28787)

56 ((digital* or manual*) adj3 (feedback* or palpat* or assess* or contract*).ti,ab,kf. (18676)

57 (pressure* adj3 perin?ometr*).ti,ab,kf. (43)

58 ((strength* or resistan*) adj3 (training or exercise* or physiotherap*).ti,ab,kf. (93150)

59 (manual adj3 therap*).ti,ab,kf. (12858)

60 (myofascia* adj3 (release* or therap* or technique*).ti,ab,kf. (2773)

61 or/37-60 (837935)

62 36 and 61 (23694)

63 62 use coch (65)

64 economics/ (264537)

65 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (1051273)

66 economics.fs. (470080)

67 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (1273187)

68 exp "costs and cost analysis"/ (686615)

69 (cost or costs or costing or costly).ti. (333118)

70 cost effective*.ti,ab,kf. (450502)

71 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog* or increment*).ab,kf. (310801)

72 models, economic/ (15986)

73 markov chains/ or monte carlo method/ (107650)

74 (decision adj1 (tree* or analy* or model*).ti,ab,kf. (67033)

75 (markov or markow or monte carlo).ti,ab,kf. (179296)

76 quality-adjusted life years/ (56016)

77 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (112098)

78 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (194019)

79 or/64-78 (3371473)

80 62 and 79 (1592)

81 80 use medall (413)

82 exp Animals/ not Humans/ (16335908)

83 81 not 82 (413)

84 Case Reports/ or Comment.pt. or Congress.pt. (3403077)

85 83 not 84 (403)

86 80 use cctr (176)

87 (Conference Proceeding or Trial Registry Record).pt. (689266)

88 86 not 87 (94)

89 63 or 85 or 88 (562)

90 limit 89 to english language [Limit not valid in CDSR; records were retained] (538)

91 limit 90 to yr="2021 -Current" (78)

92 pelvis floor/ or pelvic floor disorder/ or exp *urine incontinence/ or *overactive bladder/ or *bladder instability/ or exp *pelvic organ prolapse/ or *rectocele/ or *feces incontinence/ or urine retention/ or defecation disorder/ or Feces Impaction/ or female sexual dysfunction/ or vaginism/ (134234)

93 (pelvi* adj (floor* or diaphragm*) adj3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).tw,kw,kf. (14021)

94 (pelvi* adj (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).tw,kw,kf. (3874)

95 ((stress* or mix* or urg* or urin*) adj5 incontinen*).ti. (42451)

96 ((bladder* or detrusor*) adj5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*).ti. (18699)

97 (urgency adj2 frequency).ti. (228)

98 ((urin* or bladder*) adj2 (urg* or frequen*).ti. (2368)

99 (SUI or OAB).ti. (2142)

100 (pelvic* adj3 organ* adj3 prolaps*).ti. (9035)

101 (urinary adj3 bladder adj3 prolaps*).ti. (39)

102 ((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) adj3 prolaps*).ti. (21981)

103 (splachnoptos* or visceroptos*).ti. (55)

104 (hernia* adj3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*).ti. (1190)

105 (urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*).ti. (2642)

106 ((f?ecal or f?eces or f?ecally or anal or anally or stool\$1 or bowel or double or def?ecat*) adj5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti. (11174)

107 (urin* adj3 (retention* or retain*)).tw,kw,kf. (37977)

108 (voiding adj (disorder* or dysfunction* or problem*)).tw,kw,kf. (9880)

109 (empty* adj disorder* adj3 (bowel* or bladder* or vesical* or stool*)).tw,kw,kf. (75)

110 ((urogeni* or anorec* or ano-rec*) adj3 dysfunction*).tw,kw,kf. (1316)

- 111 ((difficult* or delay* or irregular* or infrequen* or pain*) adj3 (def?ecat* or stool* or f?eces or bowel movement*)).tw,kw,kf. (9114)
- 112 (obstruct* adj3 def?ecat*).tw,kw,kf. (2986)
- 113 ((def?ecat* or evacuat*) adj3 (disorder* or dysfunction*)).tw,kw,kf. (3867)
- 114 outlet* dysfunction* constipa*.tw,kw,kf. (12)
- 115 (dys?ynerg* adj def?ecat*).tw,kw,kf. (870)
- 116 (pelvi* adj3 dyskines*).tw,kw,kf. (21)
- 117 pelvi* outlet* obstruct*.tw,kw,kf. (67)
- 118 anismus*.tw,kw,kf. (636)
- 119 puborectal* contract*.tw,kw,kf. (157)
- 120 ((rectal or rectum) adj3 urge*).tw,kw,kf. (673)
- 121 (female adj sex* adj (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*)).tw,kw,kf. (6288)
- 122 (obstruct* adj3 intercourse).tw,kw,kf. (13)
- 123 (vagin* adj3 laxity*).tw,kw,kf. (434)
- 124 (vagin* adj wind).tw,kw,kf. (26)
- 125 vaginismus*.tw,kw,kf. (1448)
- 126 (vagin* adj penetrat* adj disorder*).tw,kw,kf. (9)
- 127 or/92-126 (223589)
- 128 *physiotherapy/ or pelvic floor muscle training/ or kinesiotherapy/ or *muscle exercise/ or vaginal cone/ or vagina cone/ or weighted vaginal cone/ or electrostimulation/ or electrotherapy/ or transcutaneous nerve stimulation/ or magnetic stimulation/ or magnetotherapy/ or extracorporeal magnetic innervation therapy/ or feedback system/ or biofeedback/ or perineometry/ or resistance training/ (322229)
- 129 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).tw,kw,kf,dv. (267)
- 130 (pelvi* adj floor* adj (physiotherap* or physical therap*).tw,kw,kf,dv. (1320)
- 131 (PFMT or PFME or PFPT).tw,kw,kf,dv. (2703)
- 132 (kegel* or kegal* or knack*).tw,kw,kf,dv. (1773)
- 133 (physiotherap* or physical therap*).ti. (45836)
- 134 physiotherapy-led.tw,kw,kf,dv. (534)
- 135 (vagin* adj3 (cone or cones or ball or balls)).tw,kw,kf,dv. (389)
- 136 (weight adj (cone or cones)).tw,kw,kf,dv. (20)
- 137 (pelvi* adj floor* adj2 (cone or cones)).tw,kw,kf,dv. (27)
- 138 ((cone or cones) adj5 (continen* or incontinen*)).ti. (53)
- 139 ((electr* adj3 stimulat*) or electrostimulat* or electro-stimulat*).tw,kw,kf,dv. (201604)
- 140 ((transcutaneous* or percutaneous* or neuromusc* or posterior* or anterior* or tibia* or perine* or intravagin* or intra-vagin*) adj4 stimulat*).tw,kw,kf,dv. (40437)
- 141 ((magnet* or electro-magnet* or electromagnet*) adj (stimulation* or therap* or treatment* or innervation*)).tw,kw,kf,dv. (61962)
- 142 ((magnet* or electro-magnet* or electromagnet*) adj (nerve* or energ* or pelvi* floor or pelvi* muscl*) adj (stimulation* or therap* or treatment*)).tw,kw,kf,dv. (145)
- 143 (interferential* adj3 (current or currents or therap* or treatment*)).tw,kw,kf,dv. (1307)
- 144 hifem*.tw,kw,kf,dv. (156)
- 145 (biofeedback* or bio-feedback*).mp. (28787)
- 146 ((digital* or manual*) adj3 (feedback* or palpat* or assess* or contract*)).tw,kw,kf,dv. (18999)
- 147 (pressure* adj3 perin?ometr*).tw,kw,kf,dv. (43)
- 148 ((strength* or resistan*) adj3 (training or exercise* or physiotherap*)).tw,kw,kf,dv. (95962)
- 149 (manual adj3 therap*).tw,kw,kf,dv. (13158)

150 (myofascia* adj3 (release* or therap* or technique*)).tw,kw,kf,dv. (2979)
 151 or/128-150 (650923)
 152 127 and 151 (19440)
 153 Economics/ (264537)
 154 Health Economics/ or Pharmacoeconomics/ or Drug Cost/ or Drug Formulary/ (146686)
 155 Economic Aspect/ or exp Economic Evaluation/ (553154)
 156 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw,kw,kf. (1293486)
 157 exp "Cost"/ (686615)
 158 (cost or costs or costing or costly).ti. (333118)
 159 cost effective*.tw,kw,kf. (459304)
 160 (cost* adj2 (util* or efficac* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog* or increment*)).ab,kw,kf. (320415)
 161 Monte Carlo Method/ (83631)
 162 (decision adj1 (tree* or analy* or model*)).tw,kw,kf. (70428)
 163 (markov or markow or monte carlo).tw,kw,kf. (182764)
 164 Quality-Adjusted Life Years/ (56016)
 165 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw,kw,kf. (115440)
 166 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw,kw,kf. (214715)
 167 or/153-166 (2892789)
 168 152 and 167 (1371)
 169 168 use emez (825)
 170 (exp animal/ or nonhuman/) not exp human/ (11897677)
 171 169 not 170 (824)
 172 Case Report/ or conference abstract.pt. or conference review.pt. (7285374)
 173 171 not 172 (618)
 174 limit 173 to english language [Limit not valid in CDSR; records were retained] (587)
 175 limit 174 to yr="2021 -Current" (83)
 176 91 or 175 (163)
 177 176 use medall (59)
 178 176 use emez (84)
 179 176 use coch (0)
 180 176 use cctr (20)
 181 remove duplicates from 176 (100)
 [SUPPLEMENTAL SEARCH to 2021 NICE SEARCH]
 182 exp Prostatectomy/ or (prostatectom* or prostate* surger* or (prostat* adj2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesction*)) or turp or turp* or tuvp or vlap).ti,ab,kf. (142147)
 183 exp Exercise Therapy/ or Physical Therapy Modalities/ (306851)
 184 (((pelvi* adj (floor* or muscl*)) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*)).ti,ab,kf. (9778)
 185 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).ti,ab,kf. (232)
 186 (pelvi* adj floor* adj (physiotherap* or physical therap*)).ti,ab,kf. (1295)
 187 (PFMT or PFME or PFPT).ti,ab,kf. (2681)
 188 (kegel* or kegal* or knack*).ti,ab,kf. (1706)
 189 (physiotherap* or physical therap*).ti. (45836)
 190 physiotherapy-led.ti,ab,kf. (529)
 191 or/183-190 (328280)

192 182 and 191 (1533)
 193 36 and 191 (13862)
 194 ((women not men) or (female not male)).tw. (3347052)
 195 193 not 194 (5957)
 196 193 and Male/ (2623)
 197 transgender persons/ or sex reassignment surgery/ or sex reassignment procedures/ or health services for transgender persons/ (190277)
 198 (transgender* or transsexual* or gender identity or "male-to-female" or "female-to-male" or sex reassignment or gender dysphoria or trans men or cross gender* or gender reassignment or trans people or gender change or gender transition or trans female or trans women).ti,ab. (465086)
 199 (or/197-198) and 193 (113)
 200 192 or 195 or 196 or 199 (6864)
 201 200 use medall (1798)
 202 79 and 201 (87)
 203 Case Reports/ or Congress.pt. (2406204)
 204 202 not 203 (85)
 205 200 use cctr (802)
 206 (Conference proceeding or Editorial or Trial registry record).pt. (2111539)
 207 205 not 206 (462)
 208 79 and 207 (21)
 209 200 use coch,cleed (17)
 210 204 or 208 or 209 (123)
 211 limit 210 to english language [Limit not valid in CDSR; records were retained] (120)
 212 limit 211 to yr="1980 -Current" (116)
 213 exp Prostatectomy/ or (prostatectom* or prostate* surger* or (prostat* adj2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesection*)) or turp or turp* or tuvp or vlap).tw,kw,kf. (142611)
 214 physiotherapy/ or pelvic floor muscle training/ or kinesiotherapy/ or *muscle exercise/ (141255)
 215 (((pelvi* adj (floor* or muscl*)) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*).tw,kw,kf,dv. (9953)
 216 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).tw,kw,kf,dv. (267)
 217 (pelvi* adj floor* adj (physiotherap* or physical therap*).tw,kw,kf,dv. (1320)
 218 (PFMT or PFME or PFPT).tw,kw,kf,dv. (2703)
 219 (kegel* or kegal* or knack*).tw,kw,kf,dv. (1773)
 220 (physiotherap* or physical therap*).ti. (45836)
 221 physiotherapy-led.tw,kw,kf,dv. (534)
 222 or/214-221 (177311)
 223 213 and 222 (1443)
 224 127 and 222 (12610)
 225 ((women not men) or (female not male)).tw. (3347052)
 226 224 not 225 (5406)
 227 224 and Male/ (2273)
 228 exp transgender/ or sex reassignment/ (20792)
 229 (transgender* or transsexual* or gender identity or sex reassignment or gender dysphoria or cross gender* or gender reassignment or trans people or gender change or gender transition).ti,ab. (39066)
 230 (or/228-229) and 224 (25)
 231 223 or 226 or 227 or 230 (6322)

232 231 use emez (4382)
 233 167 and 232 (323)
 234 Case Report/ or conference abstract.pt. or conference review.pt. (7285374)
 235 233 not 234 (253)
 236 limit 235 to english language [Limit not valid in CDSR; records were retained] (248)
 237 limit 236 to yr="1980 -Current" (248)
 238 212 or 237 (364)
 239 238 use medall (81)
 240 238 use emez (248)
 241 238 use cctr (21)
 242 238 use coch (11)
 243 238 use cleed (3)
 244 remove duplicates from 238 (280)

CINAHL

Query Results

S1 MH("Pelvic Floor Muscles" OR "Pelvic Floor Disorders" OR "Urinary Retention" OR "Feces, Impacted" OR "Vaginismus") OR MM("Urinary Incontinence+" OR "Pelvic Organ Prolapse+" OR "Rectocele" OR "Fecal Incontinence") 17,054
 S2 (pelvi* N1 (floor* or diaphragm*) N3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)) 1,830
 S3 (pelvi* N1 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)) 2,836
 S4 TI((stress* or mix* or urg* or urin*) N5 incontinen*) 5,551
 S5 TI((bladder* or detrusor*) N5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*)) 1,657
 S6 TI(urgency N2 frequency) 21
 S7 TI((urin* or bladder*) N2 (urg* or frequen*)) 302
 S8 TI(SUI or OAB) 444
 S9 TI(pelvic* N3 organ* N3 prolaps*) 1,258
 S10 TI(urinary N3 bladder N3 prolaps*) 4
 S11 TI((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) N3 prolaps*) 2,260
 S12 TI(splanchnoptos* or visceroptos*) 0
 S13 TI(hernia* N3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)) 124
 S14 TI(urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocele* or sigmoidocele* or proctocele* or proctocoele* or rectocele* or rectocoele* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocele* or cystourethrocele* or cystourethrocoele*)
 161
 S15 TI((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat* or defaecat*) N5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti 0
 S16 (urin* N3 (retention* or retain*)) 3,230
 S17 (voiding N1 (disorder* or dysfunction* or problem*)) 635
 S18 (empty* N1 disorder* N3 (bowel* or bladder* or vesical* or stool*)) 7
 S19 ((urogeni* or anorec* or ano-rec*) N3 dysfunction*) 108

S20 ((difficult* or delay* or irregular* or infrequen* or pain*) N3 (defecat* or defaecat* or stool* or faeces or feces or bowel movement*)) 809

S21 (obstruct* N3 (defecat* or defaecat*)) 130

S22 ((defecat* or defaecat* or evacuat*) N3 (disorder* or dysfunction*)) 245

S23 outlet* dysfunction* constipa* 3

S24 (dyssynerg* N1 (defecat* or defaecat*)) 42

S25 pelvi* N3 dyskines* 0

S26 pelvi* outlet* obstruct* 2

S27 anismus* 22

S28 puborectal* contract* 5

S29 ((rectal or rectum) N3 urge*) 56

S30 (female N1 sex* N1 (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*)) 3,537

S31 (obstruct* N3 intercourse) 0

S32 (vagin* N3 laxity*) 38

S33 (vagin* N1 wind) 4

S34 vaginismus* 171

S35 (vagin* N1 penetrat* N1 disorder*) 2

S36 (MH "Prostatectomy+") 751

S37 (prostatectom* or prostate* surger* or (prostat* N2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesection*)) or turp or turp* or tuvp or vlap) 1,408

S38 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 29,416

S39 MH ("Muscle Strengthening" OR "Kegel Exercises" OR "Physical Therapy+") 159,148

S40 (((pelvi* N1 (floor* or muscl*)) or PFM*) N3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*)) 1,567

S41 (pelvi* N1 floor* N1 muscl* N1 (physiotherap* or therap* or treatment)) 74

S42 (pelvi* N1 floor* N1 (physiotherap* or physical therap*)) 159

S43 (PFMT or PFME or PFPT) 263

S44 (kegel* or kegal* or knack*) 2,120

S45 TI(physiotherap* or physical therap*) 21,796

S46 physiotherapy-led 131

S47 S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 170,127

S48 S38 AND S47 3,702

S49 (MH "Economics") 14,205

S50 (MH "Economic Aspects of Illness") 11,064

S51 (MH "Economic Value of Life") 667

S52 MH "Economics, Dental" 144

S53 MH "Economics, Pharmaceutical" 2,361

S54 MW "ec" 191,231

S55 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmaco-economic* or pharmaco-economic*) 342,467

S56 (MH "Costs and Cost Analysis+") 132,546

S57 TI cost* 62,008

S58 (cost effective*) 51,043

S59 AB (cost* N2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)) 40,279
 S60 (decision N1 (tree* or analy* or model*)) 11,604
 S61 (markov or markow or monte carlo) 7,776
 S62 (MH "Quality-Adjusted Life Years") 5,992
 S63 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs) 15,201
 S64 ((adjusted N1 (quality or life)) or (willing* N2 pay) or sensitivity analysis or sensitivity analyses) 25,304
 S65 S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 472,425
 S66 S48 AND S65 211
 S67 PT (Case Study or Proceedings) 540,428
 S68 S66 NOT S67 197
 S69 Limiters - Published Date: 20210101-20231231 32
 S70 Limiters - Narrow by Language: - English 32

Quantitative Evidence of Preferences and Values Search

Search date: June 16, 2023

Databases searched: Ovid Medline, EBSCO CINAHL

Database segment: Ovid MEDLINE(R) ALL <1946 to June 15, 2023>

Search Strategy:

-
- 1 Pelvic Floor/ or Pelvic Floor Disorders/ or exp *Urinary Incontinence/ or *Urinary Bladder, Overactive/ or exp *Pelvic Organ Prolapse/ or *Rectocele/ or *Fecal Incontinence/ or Urinary Retention/ or Fecal Impaction/ or Vaginismus/ (58488)
 - 2 (pelvi* adj (floor* or diaphragm*) adj3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).ti,ab,kf. (4364)
 - 3 (pelvi* adj (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).ti,ab,kf. (918)
 - 4 ((stress* or mix* or urg* or urin*) adj5 incontinen*).ti. (16266)
 - 5 ((bladder* or detrusor*) adj5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*).ti. (6151)
 - 6 (urgency adj2 frequency).ti. (82)
 - 7 ((urin* or bladder*) adj2 (urg* or frequen*)).ti. (791)
 - 8 (SUI or OAB).ti. (467)
 - 9 (pelvic* adj3 organ* adj3 prolaps*).ti. (2982)
 - 10 (urinary adj3 bladder adj3 prolaps*).ti. (22)
 - 11 ((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) adj3 prolaps*).ti. (8806)
 - 12 (splanchnoptos* or visceroptos*).ti. (40)
 - 13 (hernia* adj3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)).ti. (616)
 - 14 (urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*).ti. (1068)

- 15 ((f?ecal or f?eces or f?ecally or anal or anally or stool\$1 or bowel or double or def?ecat*) adj5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti. (4176)
- 16 (urin* adj3 (retention* or retain*)).ti,ab,kf. (12707)
- 17 (voiding adj (disorder* or dysfunction* or problem*)).ti,ab,kf. (3326)
- 18 (empty* adj disorder* adj3 (bowel* or bladder* or vesical* or stool*)).ti,ab,kf. (33)
- 19 ((urogeni* or anorec* or ano-rec*) adj3 dysfunction*).ti,ab,kf. (464)
- 20 ((difficult* or delay* or irregular* or infrequen* or pain*) adj3 (def?ecat* or stool* or f?eces or bowel movement*)).ti,ab,kf. (2649)
- 21 (obstruct* adj3 def?ecat*).ti,ab,kf. (923)
- 22 ((def?ecat* or evacuat*) adj3 (disorder* or dysfunction*)).ti,ab,kf. (1320)
- 23 outlet* dysfunction* constipa*.ti,ab,kf. (4)
- 24 (dys?ynerg* adj def?ecat*).ti,ab,kf. (229)
- 25 (pelvi* adj3 dyskines*).ti,ab,kf. (10)
- 26 pelvi* outlet* obstruct*.ti,ab,kf. (25)
- 27 anismus*.ti,ab,kf. (205)
- 28 puborectal* contract*.ti,ab,kf. (60)
- 29 ((rectal or rectum) adj3 urge*).ti,ab,kf. (206)
- 30 (female adj sex* adj (dysfunct* or satisf* or problem* or symptom* or arouse* or activit* or disorder*)).ti,ab,kf. (2112)
- 31 (obstruct* adj3 intercourse).ti,ab,kf. (6)
- 32 (vagin* adj3 laxity*).ti,ab,kf. (115)
- 33 (vagin* adj wind).ti,ab,kf. (9)
- 34 vaginismus*.ti,ab,kf. (467)
- 35 (vagin* adj penetrat* adj disorder*).ti,ab,kf. (3)
- 36 exp Prostatectomy/ or (prostatectom* or prostate* surger* or (prostat* adj2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesction*)) or turp or turp* or tuvp or vlap).ti,ab,kf. (51896)
- 37 or/1-36 (131769)
- 38 exp Exercise Therapy/ or Physical Therapy Modalities/ (100737)
- 39 (((pelvi* adj (floor* or muscl*)) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*)).ti,ab,kf. (2767)
- 40 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).ti,ab,kf. (59)
- 41 (pelvi* adj floor* adj (physiotherap* or physical therap*)).ti,ab,kf. (294)
- 42 (PFMT or PFME or PFPT).ti,ab,kf. (726)
- 43 (kegel* or kegal* or knack*).ti,ab,kf. (486)
- 44 (physiotherap* or physical therap*).ti. (17504)
- 45 physiotherapy-led.ti,ab,kf. (132)
- 46 or/38-45 (108746)
- 47 37 and 46 (3818)
- 48 Attitude to Health/ (85424)
- 49 Health Knowledge, Attitudes, Practice/ (126458)
- 50 Patient Participation/ (29375)
- 51 Patient Preference/ (10648)
- 52 Attitude of Health Personnel/ (131357)
- 53 *Professional-Patient Relations/ (12486)
- 54 *Physician-Patient Relations/ (37263)
- 55 Choice Behavior/ (34915)

56 (choice or choices or value* or valuation* or knowledg*).ti. (319686)
 57 (preference* or expectation* or attitude* or acceptab* or point of view).ti,ab,kf. (737428)
 58 ((clinician* or doctor* or (health* adj2 worker*) or patient*1 or personal or midwi* or nurse* or physician* or physiotherapist* or practitioner* or professional*1 or provider* or user*1 or women or men) adj2 (participation or perspective* or perception* or misperception* or perceiv* or view* or understand* or misunderstand* or value*1 or knowledg*)).ti,ab,kf. (201051)
 59 health perception*.ti,ab,kf. (3347)
 60 *Decision Making/ (46493)
 61 (clinician* or doctor* or (health* adj2 worker*) or patient*1 or personal or midwi* or nurse* or physician* or physiotherapist* or practitioner* or professional*1 or provider* or user*1 or women or men).ti. (3075304)
 62 60 and 61 (9147)
 63 (decision* and mak*).ti. (37446)
 64 (decision mak* or decisions mak*).ti,ab,kf. (209770)
 65 63 or 64 (211433)
 66 (clinician* or doctor* or (health* adj2 worker*) or patient*1 or personal or midwi* or nurse* or physician* or physiotherapist* or practitioner* or professional*1 or provider* or user*1 or women or men).ti,ab,kf. (9984390)
 67 65 and 66 (134258)
 68 (discrete choice* or decision board* or decision analy* or decision-support or decision tool* or decision aid* or latent class* or decision* conflict* or decision* regret*).ti,ab,kf. (51206)
 69 Decision Support Techniques/ (22464)
 70 (health and utilit*).ti. (1956)
 71 (gamble* or prospect theory or health utilit* or utility value* or utility score* or utility estimate* or health state or feeling thermometer* or best-worst scaling or time trade-off or TTO or probability trade-off).ti,ab,kf. (17048)
 72 (preference based or preference score* or preference elicitation or multiattribute or multi attribute).ti,ab,kf. (3800)
 73 or/48-59,62,67-72 (1584762)
 74 47 and 73 (415)
 75 Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt. (4338604)
 76 74 not 75 (409)
 77 limit 76 to english language (383)
 78 limit 77 to yr="1980 -Current" (383)

CINAHL

#	Query	Results
S81	S80 Narrow by Language: - english	365
S80	s78 not s79	394
S79	PT (Case Study or Commentary or Editorial or Letter or Proceedings)	1,350,064
S78	S48 AND S77	418
S77	S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S66 OR S71 OR S72 OR S73 OR S74 OR S75 OR S76	919,547
S76	(preference based or preference score* or preference elicitation or multiattribute or multi attribute)	1,838
S75	(gamble* or prospect theory or health utilit* or utility value* or utility score* or utility estimate* or health state or feeling thermometer* or best worst scaling or time trade off or TTO or probability trade off)	20,920

S74 TI (health and utilit*) 1,170
 S73 (MH "Decision Support Techniques") 7,713
 S72 (discrete choice* or decision board* or decision analy* or decision support or decision tool* or decision aid* or latent class* or decision* conflict* or decision* regret*) 36,598
 S71 S69 AND S70 128,741
 S70 (clinician* or doctor* or (health* N2 worker*) or patient or patients or personal or midwi* or nurse* or physician* or physiotherapist* or practitioner* or professional or professionals or provider* or user or users or women or men) 3,880,694
 S69 S67 OR S68 179,753
 S68 (decision mak* or decisions mak*) 179,524
 S67 TI (decision* and mak*) 21,549
 S66 S64 AND S65 5,510
 S65 TI (clinician* or doctor* or (health* N2 worker*) or patient or patients or personal or midwi* or nurse* or physician* or physiotherapist* or practitioner* or professional or professionals or provider* or user or users or women or men) 1,410,449
 S64 (MM "Decision Making") 25,584
 S63 (MH "Decision Making, Family") 4,198
 S62 (MH "Decision Making, Patient") 15,482
 S61 (MH "Decision Making, Shared") 3,375
 S60 health perception* 5,300
 S59 ((clinician* or doctor* or (health* N2 worker*) or patient or patients or personal or midwi* or nurse* or physician* or physiotherapist* or practitioner* or professional or professionals or provider* or user or users or women or men) N2 (knowledg* or misperception* or misunderstand* or participation or perceiv* or perception* or perspective* or understand* or value or values or view*)) 181,662
 S58 (preference* or expectation* or attitude* or acceptab* or point of view) 550,860
 S57 TI (choice or choices or value* or valuation* or knowledg*) 116,100
 S56 (MM "Nurse-Patient Relations") 14,630
 S55 (MM "Physician-Patient Relations") 17,288
 S54 (MM "Professional-Patient Relations") 14,353
 S53 (MH "Attitude of Health Personnel") 53,601
 S52 (MH "Patient Preference") 2,494
 S51 (MH "Consumer Participation") 23,882
 S50 (MH "Health Knowledge") 36,540
 S49 (MH "Attitude to Health") 49,007
 S48 S38 AND S47 3,711
 S47 S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 170,609
 S46 physiotherapy-led 132
 S45 TI(physiotherap* or physical therap*) 21,835
 S44 (kegel* or kegal* or knack*) 2,124
 S43 (PFMT or PFME or PFPT) 263
 S42 (pelvi* N1 floor* N1 (physiotherap* or physical therap*)) 160
 S41 (pelvi* N1 floor* N1 muscl* N1 (physiotherap* or therap* or treatment)) 74
 S40 (((pelvi* N1 (floor* or muscl*)) or PFM*) N3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*)) 1,568
 S39 MH ("Muscle Strengthening" OR "Kegel Exercises" OR "Physical Therapy+") 159,632
 S38 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 29,552

S37 (prostatectom* or prostate* surger* or (prostat* N2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesction*)) or turp or turp* or tuvp or vlap) 1,464

S36 (MH "Prostatectomy+") 768

S35 (vagin* N1 penetrat* N1 disorder*) 2

S34 vaginismus* 171

S33 (vagin* N1 wind) 4

S32 (vagin* N3 laxity*) 40

S31 (obstruct* N3 intercourse) 0

S30 (female N1 sex* N1 (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*)) 3,542

S29 ((rectal or rectum) N3 urge*) 56

S28 puborectal* contract* 5

S27 anismus* 22

S26 pelvi* outlet* obstruct* 2

S25 pelvi* N3 dyskines* 0

S24 (dyssynerg* N1 (defecat* or defaecat*)) 42

S23 outlet* dysfunction* constipa* 3

S22 ((defecat* or defaecat* or evacuat*) N3 (disorder* or dysfunction*)) 245

S21 (obstruct* N3 (defecat* or defaecat*)) 130

S20 ((difficult* or delay* or irregular* or infrequen* or pain*) N3 (defecat* or defaecat* or stool* or faeces or feces or bowel movement*)) 811

S19 ((urogeni* or anorec* or ano-rec*) N3 dysfunction*) 109

S18 (empty* N1 disorder* N3 (bowel* or bladder* or vesical* or stool*)) 7

S17 (voiding N1 (disorder* or dysfunction* or problem*)) 633

S16 (urin* N3 (retention* or retain*)) 3,235

S15 TI((faecal or fecal or faeces or feces or fecally or faecally or anal or anally or stool or stools or bowel or double or defecat* or defaecat*) N5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti 0

S14 TI(urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocoele* or proctocoele* or proctocoele* or rectocoele* or rectocoele* or cystocoele* or cystocoele* or rectoenterocoele* or rectoenterocoele* or cystourethrocele* or cystourethrocoele*) 163

S13 TI(hernia* N3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)) 124

S12 TI(splanchnoptos* or visceroptos*) 0

S11 TI((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) N3 prolaps*) 2,269

S10 TI(urinary N3 bladder N3 prolaps*) 4

S9 TI(pelvic* N3 organ* N3 prolaps*) 1,265

S8 TI(SUI or OAB) 448

S7 TI((urin* or bladder*) N2 (urg* or frequen*)) 303

S6 TI(urgency N2 frequency) 21

S5 TI((bladder* or detrusor*) N5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*)) 1,666

S4 TI((stress* or mix* or urg* or urin*) N5 incontinen*) 5,573

S3 (pelvi* N1 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)) 2,852

S2 (pelvi* N1 (floor* or diaphragm*) N3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)) 1,842

S1 MH("Pelvic Floor Muscles" OR "Pelvic Floor Disorders" OR "Urinary Retention" OR "Feces, Impacted" OR "Vaginismus") OR MM("Urinary Incontinence+" OR "Pelvic Organ Prolapse+" OR "Rectocele" OR "Fecal Incontinence") 17,109

Grey Literature Search

Performed on: June 23 to 29, 2023

Websites searched:

Alberta Health Evidence Reviews, Alberta Health Services, BC Health Technology Assessments, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), Ontario Health Technology Assessment Committee (OHTAC), McGill University Health Centre Health Technology Assessment Unit, Centre Hospitalier de l'Université de Québec-Université Laval, Contextualized Health Research Synthesis Program of Newfoundland (CHRSP), Health Canada Medical Device Database, Health Technology Assessment Database (INAHTA), Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, Centers for Medicare & Medicaid Services Technology Assessments, Veterans Affairs Health Services Research and Development, Institute for Clinical and Economic Review, Oregon Health Authority Health Evidence Review Commission, Washington State Health Care Authority Health Technology Reviews, National Institute for Health and Care Excellence (NICE), Healthcare Improvement Scotland, Health Technology Wales, Ireland Health Information and Quality Authority Health Technology Assessments, Australian Government Medical Services Advisory Committee, Australian Safety and Efficacy Register of New Interventional Procedures -Surgical (ASERNIP-S), Italian National Agency for Regional Health Services, Belgian Health Care Knowledge Centre, Ludwig Boltzmann Institute for Health Technology Assessment, Swedish Agency for Health Technology Assessment and Assessment of Social Services, Ministry of Health Malaysia Health Technology Assessment Section, Tuft's Cost-Effectiveness Analysis Registry, PROSPERO, EUnetHTA, ClinicalTrials.gov

Keywords used: pelvic, pelvic floor, pelvic training, pelvic exercise, pelvic strength, muscle training, PFMT, physiotherapy, biofeedback, incontinence, prolapse, leak, urinary, fecal, faecal

Clinical results (included in PRISMA): 35
Economic results (included in PRISMA): 40
Ongoing HTAs (PROSPERO/EUnetHTA): 43
Ongoing clinical trials: 113

Search for Intervention-Related Health State Utilities

Search date: May 26, 2023

Database searched: Ovid MEDLINE

Database segment: Ovid MEDLINE(R) ALL <1946 to May 25, 2023>

Search Strategy:

- 1 Pelvic Floor/ or Pelvic Floor Disorders/ or exp *Urinary Incontinence/ or *Urinary Bladder, Overactive/ or exp *Pelvic Organ Prolapse/ or *Rectocele/ or *Fecal Incontinence/ or Urinary Retention/ or Fecal Impaction/ or Vaginismus/ (58360)
- 2 (pelvi* adj (floor* or diaphragm*) adj3 (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or change* or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).ti,ab,kf. (4341)
- 3 (pelvi* adj (dysfunction* or disorder* or fail* or impair* or incompeten* or insufficien* or dyssynerg* or symptom* or laxity or care* or health* or wellbeing* or well-being* or prevent* or rehabilitat* or weak* or hypertonic* or overactiv* or over-activ*)).ti,ab,kf. (914)
- 4 ((stress* or mix* or urg* or urin*) adj5 incontinen*).ti. (16221)
- 5 ((bladder* or detrusor*) adj5 (overactiv* or over-activ* or instabilit* or hyper-reflex* or hyperreflex* or incontinen*).ti. (6136)
- 6 (urgency adj2 frequency).ti. (82)
- 7 ((urin* or bladder*) adj2 (urg* or frequen*)).ti. (790)
- 8 (SUI or OAB).ti. (462)
- 9 (pelvic* adj3 organ* adj3 prolaps*).ti. (2965)
- 10 (urinary adj3 bladder adj3 prolaps*).ti. (22)
- 11 ((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder* or cervi* or rectal or rectum) adj3 prolaps*).ti. (8773)
- 12 (splanchnoptos* or visceroptos*).ti. (40)
- 13 (hernia* adj3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)).ti. (616)
- 14 (urethroc?ele* or enteroc?ele* or sigmoidoc?ele* or proctoc?ele* or rectoc?ele* or cystoc?ele* or rectoenteroc?ele* or cystourethroc?ele*).ti. (1066)
- 15 ((f?ecal or f?eces or f?ecally or anal or anally or stool\$1 or bowel or double or def?ecat*) adj5 (incontinence or incontinent or urge* or leak or leaking or leakage or soiling or seeping or seepage or impacted or impaction)).ti. (4166)
- 16 (urin* adj3 (retention* or retain*)).ti,ab,kf. (12669)
- 17 (voiding adj (disorder* or dysfunction* or problem*)).ti,ab,kf. (3320)
- 18 (empty* adj disorder* adj3 (bowel* or bladder* or vesical* or stool*)).ti,ab,kf. (33)
- 19 ((urogeni* or anorec* or ano-rec*) adj3 dysfunction*).ti,ab,kf. (463)
- 20 ((difficult* or delay* or irregular* or infrequen* or pain*) adj3 (def?ecat* or stool* or f?eces or bowel movement*)).ti,ab,kf. (2641)
- 21 (obstruct* adj3 def?ecat*).ti,ab,kf. (924)
- 22 ((def?ecat* or evacuat*) adj3 (disorder* or dysfunction*)).ti,ab,kf. (1319)
- 23 outlet* dysfunction* constipa*.ti,ab,kf. (4)
- 24 (dys?ynerg* adj def?ecat*).ti,ab,kf. (228)
- 25 (pelvi* adj3 dyskines*).ti,ab,kf. (10)
- 26 pelvi* outlet* obstruct*.ti,ab,kf. (25)
- 27 anismus*.ti,ab,kf. (203)
- 28 puborectal* contract*.ti,ab,kf. (60)
- 29 ((rectal or rectum) adj3 urge*).ti,ab,kf. (206)

- 30 (female adj sex* adj (dysfunct* or satisf* or problem* or symptom* or arous* or activit* or disorder*)).ti,ab,kf. (2101)
- 31 (obstruct* adj3 intercourse).ti,ab,kf. (6)
- 32 (vagin* adj3 laxity*).ti,ab,kf. (114)
- 33 (vagin* adj wind).ti,ab,kf. (9)
- 34 vaginismus*.ti,ab,kf. (465)
- 35 (vagin* adj penetrat* adj disorder*).ti,ab,kf. (3)
- 36 exp Prostatectomy/ or (prostatectom* or prostate* surger* or (prostat* adj2 (trans-urethral or transurethral or laser ablat* or transurethral resection* or electroresection* or transurethral electrovaporization* or transurethral vaporesction*)) or turp or turp* or tuvp or vlap).ti,ab,kf. (51753)
- 37 or/1-36 (131419)
- 38 exp Exercise Therapy/ or Physical Therapy Modalities/ (100524)
- 39 (((pelvi* adj (floor* or muscl*) or PFM*) adj3 (training or exercise* or re-training or retraining or rehabilitat* or strengthen*).ti,ab,kf. (2763)
- 40 (pelvi* adj floor* adj muscl* adj (physiotherap* or therap* or treatment)).ti,ab,kf. (59)
- 41 (pelvi* adj floor* adj (physiotherap* or physical therap*).ti,ab,kf. (292)
- 42 (PFMT or PFME or PFPT).ti,ab,kf. (720)
- 43 (kegel* or kegal* or knack*).ti,ab,kf. (485)
- 44 (physiotherap* or physical therap*).ti. (17447)
- 45 physiotherapy-led.ti,ab,kf. (131)
- 46 or/38-45 (108487)
- 47 37 and 46 (3813)
- 48 37 and 47 (3813)
- 49 Quality-Adjusted Life Years/ (15628)
- 50 (quality adjusted or adjusted life year*).ti,ab,kf. (23104)
- 51 (qaly* or qald* or qale* or qtime*).ti,ab,kf. (14432)
- 52 (illness state\$1 or health state\$1).ti,ab,kf. (8291)
- 53 (hui or hui1 or hui2 or hui3).ti,ab,kf. (1957)
- 54 (multiattribute* or multi attribute*).ti,ab,kf. (1290)
- 55 (utility adj3 (score\$1 or valu* or health* or cost* or measure* or disease* or mean or gain or gains or index*).ti,ab,kf. (19215)
- 56 utilities.ti,ab,kf. (9291)
- 57 (eq-5d or eq5d or eq-5 or eq5 or euro qual or euroqual or euro qual5d or euroqual5d or euro qol or euroqol or euro qol5d or euroqol5d or euro quol or euroquol or euro quol5d or euroquol5d or eur qol or eurqol or eur qol5d or eurqol5d or euro?qul or eur?qul5d or euro* quality of life or European qol).ti,ab,kf. (17029)
- 58 (euro* adj3 (5 d or 5d or 5 dimension* or 5dimension* or 5 domain* or 5domain*).ti,ab,kf. (5891)
- 59 (sf36* or sf 36* or sf thirtysix or sf thirty 6).ti,ab,kf. (26390)
- 60 (time trade off\$1 or time tradeoff\$1 or tto or timetradeoff\$1).ti,ab,kf. (2354)
- 61 ((qol or hrqol or quality of life).ti. or *quality of life/) and ((qol or hrqol* or quality of life) adj2 (increas* or decreas* or improve* or declin* or reduc* or high* or low* or effect or effects of worse or score or scores or change\$1 or impact\$1 or impacted or deteriorate\$)).ab. (44064)
- 62 Cost-Benefit Analysis/ and (cost effectiveness ratio* and (perspective* or life expectanc*).ti,ab,kf. (5166)
- 63 *quality of life/ and (quality of life or qol).ti. (63933)
- 64 quality of life/ and ((quality of life or qol) adj3 (improve* or chang*).ti,ab,kf. (36371)
- 65 quality of life/ and ((quality of life or qol) adj (score\$1 or measure\$1)).ti,ab,kf. (15413)
- 66 quality of life/ and health-related quality of life.ti,ab,kf. (44295)

- 67 quality of life/ and ec.fs. (10875)
- 68 quality of life/ and (health adj3 status).ti,ab,kf. (11630)
- 69 (quality of life or qol).ti,ab,kf. and cost-benefit analysis/ (16773)
- 70 models, economic/ (11067)
- 71 or/49-70 (211949)
- 72 48 and 71 (320)
- 73 Case Reports/ or Congress.pt. (2404394)
- 74 72 not 73 (318)
- 75 limit 74 to english language (305)
- 76 limit 75 to yr="1980 -Current" (305)

Appendix 2: Selected Excluded Studies

Clinical Evidence

For transparency, we provide a list of studies that readers might have expected to see but that did not meet the inclusion criteria, along with the primary reason for exclusion.

Citation	Primary reason for exclusion
Chmielewska D, Stania M, Kucab-Klich K, Błaszczak E, Kwaśna K, Smykla A, et al. Electromyographic characteristics of pelvic floor muscles in women with stress urinary incontinence following sEMG-assisted biofeedback training and Pilates exercises. <i>PLoS One</i> . 2019;14(12):e0225647.	Incorrect interventions, pilates not included
Davenport MH, Nagpal TS, Mottola MF, Skow RJ, Riske L, Poitras VJ, et al. Prenatal exercise (including but not limited to pelvic floor muscle training) and urinary incontinence during and following pregnancy: have to have pelvic floor dysfunction at baseline a systematic review and meta-analysis. <i>Br J Sports Med</i> . 2018 Nov;52(21):1397–1404. Erratum in: <i>Br J Sports Med</i> . 2019 Jan;53(2):e1. Erratum in: <i>Br J Sports Med</i> . 2020 Mar;54(5):e3.	Incorrect population, women did not have to have pelvic floor dysfunction at baseline
De Berker HT., Vogel I, McCabe G, Torkington, JH, Cornish, JA, Systematic review: a critical appraisal of conservative treatments for faecal incontinence. <i>Colorectal Dis [Special Issue: Association of Coloproctology of Great Britain and Ireland Annual Meeting, 6–8 July 2020, Edinburgh, UK]</i> 2020;22(S1):13–64.	Abstract only
Giroux M, Funk S, Karreman E, Kamencic H, Bhargava R. A randomized comparison of training programs using a pelvic model designed to enhance pelvic floor examination in patients presenting with chronic pelvic pain. <i>Int Urogynecol J</i> . 2021;32(2):423–431.	Incorrect population, pelvic pain.
Joseph, AC, Chang, MK. Comparison of behavior therapy methods for urinary incontinence following prostate surgery: a pilot study. <i>Urol Nurs</i> . 2000;20(3):203–204.	Incorrect comparison, PFMT not a comparator
Robinson JP, Bradway CW, Nuamah I, Pickett M, McCorkle R. Systematic pelvic floor training for lower urinary tract symptoms post-prostatectomy: a randomized clinical trial. <i>In J Urol Nurs</i> . 2008;2(1):3–13.	Incorrect population, randomization occurred prior to surgery

Economic Evidence

For transparency, we provide a list of studies that readers might have expected to see but that did not meet the inclusion criteria, along with the primary reason for exclusion.

Citation	Primary reason for exclusion
Von Barga E, Patterson D. Cost utility of the treatment of stress urinary incontinence. <i>Female Pelvic Med Reconstr Surg</i> . 2015;21(3):150–3..	The costs and QALYs of PFMT and usual care strategies, and the ICERs of PFMT versus usual care were not reported.
Richardson ML, Sokol ER. A cost-effectiveness analysis of conservative versus surgical management for the initial treatment of stress urinary incontinence. <i>Am J Obstet Gynecol</i> . 2014;211(5):565.e1–6	The costs and QALYs of PFMT and pessary strategies, and the ICERs of PFMT versus pessary were not reported.
Sung VW, Borello-France D, Newman DK, et al. Effect of behavioral and pelvic floor muscle therapy combined with surgery vs surgery alone on incontinence symptoms among women with mixed urinary incontinence: the ESTEEM randomized clinical trial. <i>JAMA</i> . 2019 Sep 17;322(11):1066–1076	The comparator is the surgical treatment.
Harvie HS, Sung VW, Neuwahl SJ, et al. Cost-effectiveness of behavioral and pelvic floor muscle therapy combined with midurethral sling surgery vs surgery alone among women with mixed urinary incontinence: results of the Effects of Surgical Treatment Enhanced With Exercise for Mixed Urinary Incontinence randomized trial. <i>Am J Obstet Gynecol</i> . 2021 Dec;225(6):651.e1–651.e26.	The comparison is the surgical treatment.
Cacciari LP, Kouakou CR, Poder TG, et al. Group-based pelvic floor muscle training is a more cost-effective approach to treat urinary incontinence in older women: economic analysis of a randomised trial. <i>J Physiother</i> . 2022 Jul;68(3):191–196	Group-based versus individual pelvic floor muscle training.
Ontario Health (Quality). Vaginal pessaries for pelvic organ prolapse or stress urinary incontinence: a health technology assessment. <i>Ont Health Technol Assess Ser</i> . 2021 May 6;21(3):1–155	All treatment pathways included surgery.
Imamura M, Abrams P, Bain C, et al. Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. <i>Health Technol Assess</i> . 2010 Aug;14(40):1–188, iii-iv	All treatment pathways included surgery.
Sjöström M, Lindholm L, Samuelsson E. Mobile app for treatment of stress urinary incontinence: a cost-effectiveness analysis. <i>J Med Internet Res</i> . 2017 May 8;19(5):e154	Mobile app-based pelvic floor muscle training was likely to be unsupervised (based on the description of this program).
Ekersund J, Samuelsson E, Lindholm L, Sjöström M. A mobile app for the treatment of female mixed and urgency incontinence: a cost-effectiveness analysis in Sweden. <i>Int Urogynecol J</i> . 2022 May;33(5):1273–1282	Mobile app-based pelvic floor muscle training was likely to be unsupervised (based on the description of this program).
Fenocchi L, Best C, Mason H, et al. Long-term effects and costs of pelvic floor muscle training for prolapse: trial follow-up record-linkage study. <i>Int Urogynecol J</i> . 2023 Jan;34(1):239–246	The costs during trial time were not reported. Posttrial health outcomes period not reported.
Hullfish KL, Trowbridge ER, Stukenborg GJ. Treatment strategies for pelvic organ prolapse: a cost-effectiveness analysis. <i>International Urogynecology Journal</i> . 2011;22(5):507–15.	The pelvic floor muscle therapy strategy was not included.
Glazener C, Boachie C, Buckley B, et al. Urinary incontinence in men after formal one-to-one pelvic-floor muscle training following radical prostatectomy or transurethral resection of the prostate (MAPS): two parallel randomised controlled trials. <i>Lancet</i> . 2011;378(9788):328–337.	The findings of 2 trials were reported with greater details in another paper, ⁸⁸ which was included in our review.

Appendix 3: Characteristics of Included Studies

Table A1: Characteristics of Included Studies

Author, year, type	Number of RCTs	Population	Intervention	Comparator	Outcomes	Type of risk of bias assessment
Systematic reviews						
NICE 2021 ¹						
Systematic reviews						
Ge et al, ⁸¹ 2020	2	Women with POP	PFMT	Pessary (1 study), support device (1 study)	Self-reported change in symptoms	Jadad scoring checklist
Hagen et al, ⁷⁸ 2011	3	Women with POP	PFMT	No treatment	Improvement in symptoms, quality of life, satisfaction	Cochrane risk of bias tool
Dumoulin et al, ⁵⁹ 2018	31	Women with SUI, UUI, or mixed UI	PFMT	No treatment, placebo or sham treatments, or other inactive control treatments	Subjective change in continence, quality of life, satisfaction	Cochrane risk of bias tool
Herbison et al, ⁶⁴ 2013	11	Women with SUI	PFMT	Cones	Improvement of symptoms	Cochrane risk of bias tool
Imamura et al, ⁶⁰ 2010	27	Women with SUI	PMFT	No treatment (14 studies), electrical stimulation (7 studies), vaginal cones (6 studies)	Improvement of symptoms, quality of life	Checklist by Cochrane Incontinence Group (adapted version)
Liang et al, ^{67,a} 2018	6	Women with SUI	PFMT	Electrical stimulation (2 studies), vaginal cones (4 studies)	Quality of life	Unnamed checklist ^c
Moroni et al, ⁶⁵ 2016	4	Women with SUI	PFMT	No treatment (2 studies), vaginal cones (2 studies)	Quality of life	Jadad scale
Nie et al, 2017	12	Women with SUI	PFMT	No treatment	Improvement of symptoms, quality of life	"2012 Cochrane guidelines"
Oblasser et al, 2015	1 ^d	Women with SUI 3 mo postpartum	PFMT	Vaginal cones	Improvement of symptoms	Cochrane risk of bias tool
Stewart et al, ⁶³ 2017	9	Women with SUI	PFMT	Electrical stimulation	Improvement of symptoms, quality of life	Cochrane risk of bias tool

Author, year, type	Number of RCTs	Population	Intervention	Comparator	Outcomes	Type of risk of bias assessment
Woodley et al, ⁶⁶ 2020	NR	Women, antenatal or postnatal, with SUI or FI	PFMT	No PFMT, usual care, or unspecified control	Quality of life	Cochrane risk of bias tool
RCTs						
Liang et al, ⁸⁰ 2019	NA	Women with POP indicated for surgery	PFMT and lifestyle advice PFMT: Initial 20–30 min appt with physiotherapist, exercise for 15–30 min 2–3×/d; same lifestyle advice as control group	Lifestyle advice alone Lifestyle advice w/ leaflet: information about condition, avoiding activities that increase abdominal pressure, treatments for chronic cough and constipation, healthy diet	Improvement of symptoms (baseline, discharge; 40 d and 60 d postsurgery)	Cochrane risk of bias tool
Nyhus et al, ⁷⁹ 2020	NA	Women with POP indicated for surgery	PFMT Information leaflet, daily PFMT (8–12 contractions, held 6–8 s, 3×/d); information and instruction; physiotherapist at 2 and 6 wk to assess contraction by vaginal palpation	No treatment (no intervention during wait for surgery)	Improvement of symptoms, recurrence of symptoms	Cochrane risk of bias tool
NICE 2021⁴⁶						
Systematic reviews						
None	—	—	—	—	—	—
RCTs						
Panman et al, ⁸² 2016	NA	Women with symptomatic POP	Pessary If discomfort or pessary fell out within the first 2 wk, refitted and reviewed after additional 2 wk; unsuccessful after 3 attempts If vaginal discharge, irritation, or erosions, advised not to use for 2 wk; if due to vaginal atrophy, topical estrogen suggested	PFMT Face to face and at home exercises (3–5×/wk, 2–3×/d); all participants started with the same exercise regimen, which was later tailored to the needs of each individual.	Improvement of symptoms, quality of life	Cochrane risk of bias tool

Author, year, type	Number of RCTs	Population	Intervention	Comparator	Outcomes	Type of risk of bias assessment
Richter et al, ⁶¹ 2010	NA	Women with SUI	Pessary: Physician- or nurse-fitted intravaginal pessary (continence ring or dish, type not specified)	PFMT and PFMT+pessary: 1 visit/2 wk; instruction on PFMT and exercise with individualized prescriptions for daily PFMT and practice. After 8 wk (4 visits), combined group could continue using PFMT alone or pessary alone	Improvement of symptoms, satisfaction	Cochrane risk of bias tool
Kenton et al, ^{62,b} 2012	NA	Women with SUI	Pessary	PFMT and PFMT+Pessary	Improvement of symptoms, quality of life	Cochrane risk of bias tool
Johnson et al, ³⁴ 2023						
Systematic reviews						
None	—	—	—	—	—	—
RCTs						
Filocamo et al, ⁶⁸ 2005	NA	Patients who underwent standard radical prostatectomy for clinical stage T1 or T2 prostate cancer	PFMT Kegel exercises after catheter removal: alternating 5 s contraction, 10 s relaxation; PFMT in sitting, standing, squatting, and going up and down stairs (7 d); contractions only before any effort that might cause urinary incontinence. Exercise program carried out by participants at home for 6 mo or longer, if needed.	Control No formal education in PFMT after catheter removal	Improvement of symptoms	Cochrane risk of bias tool
Laurienzo et al, ⁶⁹ 2018	NA	Men who underwent radical prostatectomy for prostate cancer	PFMT postoperative; 3 home exercises: elevation of the hip, contraction of thigh adductors, pelvic floor contraction and relaxation 2–3×/d for 6 mo	Routine postoperative instructions at discharge	Urinary symptoms, quality of life, urine loss	Cochrane risk of bias tool

Author, year, type	Number of RCTs	Population	Intervention	Comparator	Outcomes	Type of risk of bias assessment
Manassero et al, ⁷⁰ 2007	NA	Men who underwent radical prostatectomy for localized prostate cancer	PFMT For as long as incontinence persisted, within 1 y; active pelvic floor exercises w/ verbal feedback to instruct correct muscles and strength was measured using digital anal control (ES at home with an anal probe if not able and not included in study) Home practice initially comprised 45 contractions (3×15)/d, progressively increasing to 3×/30/d, taught by 2 experienced pelvic floor urologists.	Control Assessed on rate of residual incontinence	Incontinence rate, quality of life	
Moore et al, ⁷⁴ 1999	NA	Men who underwent radical prostatectomy	PFMT For 30 min 2/wk for 12 wk; exercises for strength, endurance, speed, control	No treatment (verbal and written instruction only)	Urine loss, number of incontinence episodes, quality of life	Cochrane risk of bias tool
Moore et al, ⁷² 2008	NA	Men who underwent radical prostatectomy for localized prostate cancer.	PFMT Postoperative booklet on recovery, w/ description of PFMT; biofeedback 30 min/wk with physiotherapist; exercise for strength, endurance, speed, and control and instructed to perform penile lift; on nontreatment days, 3×/d at home	Postoperative booklet on recovery, w/ description of PFMT	Urinary loss, urinary symptoms, quality of life	Cochrane risk of bias tool
Sanchez-Salas et al, ⁷³ 2021	NA	Men who underwent radical prostatectomy	PFMT+biofeedback Contractions with electromyographic feedback 1×/wk for 3 mo	Control Instructed about pelvic muscle contractions at home after the catheter removal	Urinary symptoms, quality of life	Cochrane risk of bias tool
Strojek et al, ⁷⁵ 2021	NA	Men who underwent radical prostatectomy for prostate cancer	PFMT In-hospital rehabilitation department 2 wk postsurgery: 24 sessions physiotherapist-guided (2×/wk for 3 mo) postural correction, co-contraction of transverse abdominal muscle standing, supine, and sitting; adjusted individually for each participant	Control No treatment	Quality of life	Cochrane risk of bias tool

Author, year, type	Number of RCTs	Population	Intervention	Comparator	Outcomes	Type of risk of bias assessment
Van Kampen et al, ⁷¹ 2000	NA	Men who underwent radical prostatectomy for localized prostate cancer	PFMT For as long as incontinence persisted, up to 1 y, outpatient 1x/wk: anatomy and function of pelvic floor and bladder explained, active pelvic floor muscle exercises and biofeedback; if not able to contract pelvic floor muscles initially, given electrical stimulation with anal probe; Once able, 90 contractions/d at home supine, sitting, or standing	Control 1x/wk placebo electrotherapy (false interferential current) via 4 skin electrodes (2 on abdomen, 2 on adductor thighs muscles)	24 hour pad test, symptoms	Cochrane risk of bias tool
Forte et al, ⁴⁷ 2016						
Systematic reviews						
None	—	—	—	—	—	—
RCTs						
Damon et al, ⁷⁷ 2014	NA	Adults with fecal incontinence	PFMT+biofeedback (20 sessions) plus standard care	Standard care (laxative, oral bulking agent)	CCFIS, FIQL, KESS, SF-12, symptom change	Cochrane risk of bias tool
Norton et al, ⁷⁶ 2003	NA	Adults with fecal incontinence	Hospital and home-based PFMT + biofeedback plus standard care; hospital based PFMT + biofeedback plus standard care; PFMT + digital rectal feedback plus standard care	Standard care Up to 9 sessions: 40–60-min over 3–6 mo w/ specialist nurse advice on diet, fluids, techniques to improve evacuation, a bowel training program, titration of dose of antidiarrheal medication (if previously prescribed), and practical management	Patient opinion of treatment effectiveness, Vaizey Fecal Incontinence Score, Bowel Symptom Questionnaire, SF-36, HAD	Cochrane risk of bias tool
RCTs						
Sahin et al, ⁵⁷ 2022	NA	Women with SUI	PFMT (at home and 2x/mo wkly) to monitor training progress and increase treatment adherence; PFMT + ES	ES and PFMT + ES: applied under supervision of physiotherapist 3 d/wk in clinic	Improvement of symptoms, quality of life, urinary incontinence episodes	Cochrane risk of bias tool

Author, year, type	Number of RCTs	Population	Intervention	Comparator	Outcomes	Type of risk of bias assessment
Dudoniene et al, ⁵⁸ 2023	NA	Women with SUI	PFMT 12 sessions (30 min 2x/wk for 6 wk): individually w/physiotherapist; sessions 1–6: exercises focusing on slow- and fast-twitch fibers, diaphragmatic breathing, transversus abdominis contraction, and strengthening of thighs, buttocks, and core muscles; sessions 7–12: 5 additional exercises in 2 sets of 10, w 30–60 s rest intervals; intensity customized for each participant	Magnetic stimulation 12 sessions (30 min 2x/wk for 6 wk); magnetic coil to feel contraction (20 min at 35 Hz, 10 min at 5 Hz)	Improvement of symptoms	Cochrane risk of bias tool

Abbreviations: PFMT, pelvic floor muscle training; POP, pelvic organ prolapse; RCT, randomized controlled trial; SUI, stress urinary incontinence.

^aWith network meta-analysis.

^bAdditional analysis of Richter et al.

^cThe checklist included: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias.

^dWith several intervention groups.

Appendix 4: Critical Appraisal of Clinical Evidence

Table A2: Risk of Bias^a Among Systematic Reviews (ROBIS Tool)

Author, year, topic	Phase 2				Phase 3
	Study eligibility criteria	Identification and selection of studies	Data collection and study appraisal	Synthesis and findings	Risk of bias in the review
NICE, ¹ 2021	Low	Low	Low	Low	Low
NICE, ⁴⁶ 2021	Low	Low	Low	Low	Low
Johnson et al, ³⁴ 2023	Low	Low	Low	Low	Low
Forte et al, ⁴⁷ 2016	Low	Low	Low	Low	Low

Abbreviation: NICE, National Institute for Clinical Excellence; ROBIS, Risk of Bias in Systematic Reviews.

^aPossible risk-of-bias levels: low, high, unclear.

Table A3: Risk of Bias^a Among Randomized Controlled Trials (Cochrane Risk-of-Bias Tool)

Author, year	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Incomplete outcome data	Selective reporting	Other bias
Dudoniene et al, ⁵⁸ 2023	Low	Low	High ^b	High ^c	Low	—
Sahin et al, ⁵⁷ 2022	Low	Low	High ^b	High ^d	Low	—

^aPossible risk-of-bias levels: low, high, and unclear.

^bNo blinding of physiotherapists or patients.

^cDropout rate 29.41%. Reasons for dropping out not reported. No intent-to-treat analysis.

^dNine of 60 included patients dropped out of study. Reasons for dropping out were reported. No intent-to-treat analysis.

Table A4: GRADE Evidence Profile – Comparison of PFMT and No Treatment (Women, Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
2 SR ^{59,60}	Serious limitations (–1) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	—	⊕⊕⊕ Moderate
Quality of life							
3 SR ^{59,60,65}	Serious limitations (–1) ^a	No serious limitations	No serious limitations	Serious limitations (–1) ^b	Undetected	—	⊕ Very Low
Patient satisfaction							
1 SR ⁵⁹	Serious limitations (–1) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	—	⊕⊕⊕ Moderate

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; SR, systematic review.

^aNICE reported serious risk of bias.

^bNICE reported 95% CI crosses 1 minimally important difference (0.5 x standard deviation control, 6.025); 95% CI crosses 1 MID (0.5 x standard deviation control, 0.84) – both in Imamura et al⁶⁰ (as reported by NICE).

Table A5: GRADE Evidence Profile – Comparison of PFMT and Pessary (Women, Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
2 RCT ^{61,62}	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	—	⊕⊕ Low
Patient satisfaction							
1 RCT ⁶¹	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	—	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; SR, systematic review.

^aBlinding was not described for participants or care providers. However, the authors stated that “outcome assessors were blinded to treatment group assignment.” PFMT patients had more clinic visits than pessary-only patients. Higher levels of clinician contact could impact on patient’s perceptions of satisfaction and improvement.

Table A6: GRADE Evidence Profile – Comparison of PFMT and Electrical Stimulation (Women, Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
2 SR ^{60,63} ; 1 RCT ⁵⁷	Very serious limitations (-2) ^a	No serious limitations	No serious limitations	Serious limitations (-1) ^b	Undetected	—	⊕ Very low
Quality of life							
1 SR ⁶⁷ ; 1 RCT ⁵⁷	Very serious limitations (-2) ^a	No serious limitations	No serious limitations	Serious limitations (-1) ^c	Undetected	—	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; SR, systematic review.

^aNICE¹ reported serious risk of bias.

^bNICE¹ reported 95% CI crosses 1 minimally important difference (ICIQ-SF, 4).

^cIn the study by Sahin et al,⁵⁷ 9 of 60 included patients dropped out of study. Reasons for dropping out were reported. No intent-to-treat analysis.

Table A7: GRADE Evidence Profile – Comparison of PFMT Plus Electrical Stimulation and Electrical Stimulation Alone (Women, Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
1 RCT ⁵⁷	Very serious limitations (-2) ^a	No serious limitations	No serious limitations	Serious limitations (-1) ^b	Undetected	—	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

^aNine of 60 included patients dropped out of study. Reasons for dropping out were reported. No intent-to-treat analysis. No blinding of patient or provider.

^bDropouts exceeded estimation in sample size calculation. Small sample size.

Table A8: GRADE Evidence Profile – Comparison of PFMT and Magnetic Stimulation (Women, Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
1 RCT ⁵⁸	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	Serious limitations (–1) ^b	Undetected	–	⊕ Very low
Complications							
1 RCT ⁵⁸	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	Serious limitations (–1) ^b	Undetected	–	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; SR, systematic review.

^aNo blinding of physiotherapists or patients. Dropout rate 29.41%. Reasons for dropping out not reported. No intent-to-treat analysis.

^bHigh dropout rate. No sample size calculation.

Table A9: GRADE Evidence Profile – Comparison of PFMT and Vaginal Cones (Women, Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
2 SR ^{64,60}	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	Serious limitations (–1) ^b	Undetected	–	⊕ Very low
Quality of life							
3 SR ^{60,65,67}	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	Serious limitations (–1) ^c	Undetected	–	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; SR, systematic review.

^aNICE¹ reported serious risk of bias.

^bNICE¹ reported the 95% CI crosses 2 minimally important differences (0.8 and 1.25).

^cWide confidence intervals and small sample size.

Table A10: GRADE Evidence Profile – Comparison of PFMT and Usual Care (Women, Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Quality of life							
1 SR ⁶⁶	Very serious limitations (-2) ^a	No serious limitations	No serious limitations	Serious limitations (-1) ^b	Undetected	—	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; SR, systematic review.

^aNICE¹ reported serious risk of bias.

^bNICE reported serious imprecision (wide confidence intervals and small sample sizes).

Table A11: GRADE Evidence Profile – Comparison of PFMT Plus Biofeedback and Electrical Stimulation (Women, Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Quality of life							
1 SR ⁶⁷	Very serious limitations (-2) ^a	No serious limitations	No serious limitations	Serious limitations (-1) ^a	Undetected	—	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; SR, systematic review.

^aNICE¹ reported serious risk of bias.

^bNICE¹ reported 95% CI crosses 1 minimally important difference (ICIQ-SF, 4).

Table A12: GRADE Evidence Profile – Comparison of Vaginal Cones and PFMT Plus Biofeedback (Women, Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Quality of life							
1 SR ⁶⁷	Very serious limitations (-2) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	—	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; SR, systematic review.

^aNICE¹ reported serious risk of bias.

Table A13: GRADE Evidence Profile – Comparison of PFMT and No Treatment, Sham, or Verbal/Written Instructions (Men, Postprostatectomy Stress Urinary Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Subjective improvement of symptoms							
2 RCTs ^{68,69}	Very serious limitations (–2) ^a	Serious limitations (–1) ^b	No serious limitations	No serious limitations	Undetected	—	⊕ Very low
Objective improvement of symptoms							
2 RCTs ^{68,70}	Very, very serious limitations (–3) ^c	No serious limitations	No serious limitations	No serious limitations	Undetected	—	⊕ Very low
Quality of life							
3 RCTs ^{69,74,75}	Very serious limitations (–2) ^a	Serious limitations (–1) ^b	No serious limitations	No serious limitations	Undetected	—	⊕ Very low
Complications							
1 RCT ⁷⁴	Very serious limitations (–2) ^d	No serious limitations	No serious limitations	Serious limitations (–1) ^e	Undetected	—	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

^aUnclear methods of randomization, no blinding of patients or outcome assessors, details of excluded patients unavailable; selective reporting of results.

^bInconsistent effects between studies.

^cNo blinding of patients or outcome assessors; not all outcomes reported; incomplete outcome data, no intent-to-treat analysis; imbalance between groups at baseline.

^dNo blinding of patients, unclear blinding of outcome assessors, selective reporting.

^eFewer than 400 participants overall.

Table A14: GRADE Evidence Profile – Comparison of PFMT Plus Biofeedback and No Treatment, Sham, or Verbal/Written Instructions (Men, Postprostatectomy Stress Urinary Incontinence) as Reported³⁴

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Subjective improvement of symptoms							
1 RCT ⁷¹	Serious limitations (-1) ^a	No serious limitations	No serious limitations	Serious limitations (-1) ^b	Undetected	—	⊕⊕ Low
Objective improvement of symptoms							
3 RCTs ^{72,73,71}	Very serious limitations (-2) ^{a,c}	No serious limitations	No serious limitations	No serious limitations	Undetected	—	⊕⊕ Low
Complications							
1 RCT ⁷²	Very serious limitations (-2) ^d	No serious limitations	No serious limitations	Serious limitations (-1) ^b	Undetected	—	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

^aConcerns about blinding of participants and personnel.

^bFewer than 400 participants overall.

^cConcerns about attrition bias and selective reporting.

^dConcerns about blinding of participants and personnel, attrition bias and selective reporting.

Table A15: GRADE Evidence Profile – Comparison of PFMT and Standard Care (Men or Nonpregnant Women, Fecal Incontinence)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
2 RCTs ^{76,77}	Very serious limitations (-2) ^a	No serious limitations	No serious limitations	Serious limitations (-1) ^b	Undetected	—	⊕ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

^aLack of detail about randomization and allocation; no blinding of participants and personnel; lack of detail regarding dropouts.

^bPatients lost to follow-up excluded from analyses.

Table A16: GRADE Evidence Profile – Comparison of PFMT and No Treatment or Inactive Control (Women, Pelvic Organ Prolapse)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
2 SR ^{78,81} ; 2 RCT ^{79,80}	Serious limitations (–1) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	–	⊕⊕⊕ Moderate
Quality of life							
1 SR ⁷⁸	Serious limitations (–1) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	–	⊕⊕⊕ Moderate
Patient satisfaction							
1 SR ⁷⁸	Serious limitations (–1) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	–	⊕⊕⊕ Moderate

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial; SR, systematic review.

^aNICE¹ reported serious risk of bias.

Table A17: GRADE Evidence Profile – Comparison of Pessary and PFMT (Women, Pelvic Organ Prolapse)

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Improvement of symptoms							
1 RCT ⁸²	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	–	⊕⊕ Low
Quality of life							
1 RCT ⁸²	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	–	⊕⊕ Low
Complications							
1 RCT ⁸²	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	Serious limitations (–1) ^b	Undetected	–	⊕ Very low
Sexual function							
1 RCT ⁸²	Very serious limitations (–2) ^a	No serious limitations	No serious limitations	No serious limitations	Undetected	–	⊕⊕ Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PFMT, pelvic floor muscle training; RCT, randomized controlled trial.

^aHigh risk of bias due to incomplete blinding (assessor blinded only) and incomplete outcome data (> 10% dropout rate). PFMT adherence unclear.

^bIncomplete outcome data, small sample size.

Appendix 5: Results of Applicability Checklists for Studies Included in the Economic Literature Review

Table A18: Assessment of the Applicability of Studies Evaluating the Cost-Effectiveness of Pelvic Floor Muscle Training

Author, year, country	Is the study population similar to the question?	Are the interventions similar to the question?	Is the health care system studied sufficiently similar to Ontario?	Were the perspectives clearly stated? If yes, what were they?	Are all direct effects included? Are all other effects included where they are material?	Are all future costs and outcomes discounted? If yes, at what rate?	Is the value of health effects expressed in terms of quality-adjusted life-years?	Are costs and outcomes from other sectors fully and appropriately measured and valued?	Overall judgment ^a
Urinary incontinence in women									
Chang et al 2022, ⁸⁵ United States	Yes	Yes	No	Yes. US health care system	Unclear	Unclear	Yes	NA	Partially applicable
Simpson et al 2019, ⁸⁶ Canada	Yes	Likely	Likely	Yes. Canadian health system	Yes	NA	Yes	NA	Partially applicable
Pelvic organ prolapse in women									
Panman et al 2017, ⁸⁷ Netherlands	Yes	Yes	No	Unclear	Yes	Unclear	Yes	NA	Partially applicable
Panman et al 2016, ⁸² Netherlands	Yes	Yes	No	Unclear	Yes	Unclear	Yes	NA	Partially applicable
Urinary incontinence in men after prostate surgery									
Glazener et al 2011, ⁸⁸ United Kingdom	Yes	Yes	No	Yes. UK NHS and societal	Yes	NA	Yes	Yes	Partially applicable
Glazener et al 2011, ⁸⁸ United Kingdom	Yes	Yes	No	Yes. UK NHS and societal	Yes	NA	Yes	Yes	Partially applicable

Abbreviations: NHS, National Health Service; UK, United Kingdom; US, United States.

Note: Response options for all items were “yes,” “partially,” “no,” “unclear,” and “NA” (not applicable).

^aOverall judgment may be “directly applicable,” “partially applicable,” or “not applicable.”

Appendix 6: Additional Data in Budget Impact Analysis

Table A19: US Prevalence Data for Symptomatic Pelvic Floor Disorders, Women

Age, years	Urinary incontinence, %	Fecal incontinence, %	Pelvic organ prolapse, %	≥ 1 disorder, %
Overall ⁹⁴	17.1	9.4	2.9	25.0
20–29	3.5	2.6	0.5	6.3
30–39	9.2	4.3	2.1	13.6
40–49	15.0	8.8	2.3	23.4
50–59	22.4	11.0	4.0	31.6
60–69	24.7	16.5	5.1	38.5
70–79	29.7	14.3	4.3	39.6
≥ 80	38.2	21.0	4.0	52.7

Source: US National Health and Nutrition Examination Survey.⁹⁴

Table A20: US Prevalence Data for Symptomatic Pelvic Floor Disorders, Men

Age, years	Prevalence, %
Urinary incontinence⁹⁵	
Overall	4.5
20–34	0.7
35–44	1.6
45–54	4.7
55–64	6.6
65–74	11.2
≥75	16.0
Fecal incontinence⁸	
Overall	7.7
20–29	3.0
30–39	5.2
40–54	7.4
55–69	9.4
≥70	15.2

Source: National Health and Nutrition Examination Survey (NHANES).^{8,95}

Table A21: Ontario Adult Population by Sex, 2018 to 2022

	2018	2019	2020	2021	2022
Women					
All adults, n	5,889,829	5,997,815	6,087,891	6,139,032	6,268,458
18 to 44 years, n	2,567,971	2,624,135	2,667,242	2,677,196	2,761,319
45 to 64 years, n	1,994,471	1,998,968	1,999,290	1,995,875	1,993,853
≥ 65 years, n	1,327,387	1,374,712	1,421,359	1,465,961	1,513,286
Men					
All adults, n	5,642,935	5,759,839	5,848,695	5,905,992	6,043,479
18 to 64 years, n	4,547,307	4,622,177	4,669,369	4,686,945	4,782,523
≥ 65 years, n	1,095,628	1,137,662	1,179,326	1,219,047	1,260,956

Note: We rearranged the categories of age group for analysis.

Source: Statistics Canada.⁹⁷

Table A22: Estimates of the Number of Adult Women With Common Pelvic Floor Disorders in Ontario in 2022

Age, years	Urinary incontinence	Fecal incontinence	Pelvic organ prolapse	≥ 1 disorder ^a	References
18 to 19 years ^b	5,814	4,319	831	10,464	94,97
20 to 24 years	17,662	13,121	2,523	31,792	94,97
25 to 29 years	18,952	14,079	2,707	34,114	94,97
30 to 34 years	49,861	23,305	11,381	73,708	94,97
35 to 39 years	47,746	22,316	10,899	70,582	94,97
40 to 44 years	73,220	42,956	11,227	114,224	94,97
45 to 49 years	71,085	41,703	10,900	110,893	94,97
50 to 54 years	108,471	53,267	19,370	153,021	94,97
55 to 59 years	117,222	57,564	20,932	165,367	94,97
60 to 64 years	126,562	84,545	26,132	197,272	94,97
65 to 69 years	110,411	73,756	22,797	172,098	94,97
70 to 74 years	110,741	53,320	16,033	147,655	94,97
75 to 79 years	83,821	40,358	12,136	111,761	94,97
80 to 84 years	73,388	40,344	7,685	101,245	94,97
85 to 89 years	47,806	26,281	5,006	65,952	94,97
90 to 94 years	25,729	14,144	2,694	35,496	94,97
95 to 99 years	8,607	4,732	901	11,874	94,97
100 years and older	1,543	848	162	2,129	94,97
Total	1,098,641	610,958	184,316	1,609,647	94,97

^aThe presence of at least 1 condition of self-reported pelvic organ prolapse, moderate-to-severe urinary incontinence, or monthly fecal incontinence.

^bWe assumed that for the 15 to 19 age group population, 40% were 18 and 19 years old. We also assumed that the prevalence rates of disorders for the people at 18 to 19 years old were the same as these in the 20 to 24 years old group.

Note: the estimates of the number of people with pelvic floor dysfunction were calculated from the numbers Ontario population in different sex and age groups⁹⁷ multiplied by the corresponding sex age group specified prevalence rates.

Source: US National Health and Nutritional Examination Survey (NHANES).⁹⁴

Table A23: Estimates of the Number of Adult Men With Common Pelvic Floor Disorders in Ontario in 2022

Age, years	Urinary incontinence	Fecal incontinence	≥ 1 disorder ^a	References
18 to 19 years ^b	1,217	5,214	5,774	8,24,95,97
20 to 24 years	3,869	16,582	18,362	8,24,95,97
25 to 29 years	4,091	17,531	19,413	8,24,95,97
30 to 34 years	3,932	29,211	29,758	8,24,95,97
35 to 39 years	8,372	27,209	31,946	8,24,95,97
40 to 44 years	7,448	34,445	37,614	8,24,95,97
45 to 49 years	20,972	33,019	48,476	8,24,95,97
50 to 54 years	22,008	34,651	50,871	8,24,95,97
55 to 59 years	33,937	48,335	73,868	8,24,95,97
60 to 64 years	32,503	46,292	70,745	8,24,95,97
65 to 69 years	45,743	38,392	75,541	8,24,95,97
70 to 74 years	36,945	50,139	78,188	8,24,95,97
75 to 79 years	38,640	36,708	67,651	8,24,95,97
80 to 84 years	23,991	22,791	42,003	8,24,95,97
85 to 89 years	13,729	13,043	24,037	8,24,95,97
90 to 94 years	5,759	5,471	10,082	8,24,95,97
95 to 99 years	1,375	1,306	2,407	8,24,95,97
100 years and over	135	128	236	8,24,95,97
Total	304,666	460,467	686,972	8,24,95,97

^aThe presence of at least 1 condition of moderate-to-severe urinary incontinence, or fecal incontinence in preceding month. The National Health and Nutrition Examination Survey 2005–2010 showed that 6.4%, 8.4%, and 1.9% ≥ 50 years old men had urinary incontinence only, fecal incontinence only, and dual incontinence, respectively.²⁴ Based on these values, we approximated that the ratio the number people with 1 or 2 disorders (i.e., unique individuals) versus the sum people with urinary incontinence and people with fecal incontinence would 0.90 which was calculated by $(6.4\% + 8.4\% + 1.9\%) \div ([6.4\% + 1.9\%] + [8.4\% + 1.9\%])$. We then estimate the total number of males with any disorder using 0.90 multiplied by the sum of number of people with urinary incontinence and the number of people fecal incontinence.

^bWe assumed that for the 15 to 19 age group population, 40% were 18 and 19 years old. We also assumed that the prevalence rates of disorders for the people at 18 to 19 years old were the same as these in the 20 to 24 years old group.

Note: the estimates of the number of people with pelvic floor dysfunction were calculated from the numbers Ontario population in different sex and age groups⁹⁷ multiplied by the corresponding sex age group specified prevalence rates.

Source: US National Health and Nutritional Examination Survey (NHANES).^{8,95}

Table A24: Regrouped Estimates of the Number of People With Common Pelvic Floor Disorders Based on Ontario Population in 2022

	Urinary incontinence	Fecal incontinence	Pelvic organ prolapse	≥ 1 disorder
Women				
All adults, n	1,098,641	610,958	184,316	1,609,647
18 to 44 years, n	213,255	120,096	39,568	334,884
45 to 64 years, n	423,340	237,079	77,334	626,553
≥ 65 years, n	462,046	253,783	67,414	648,210
Men				
All adults, n	304,666	460,467	NA	686,972
18 to 64 years, n	138,349	292,489	NA	386,827
≥ 65 years, n	166,317	167,978	NA	300,145

Abbreviations: NA, not applicable.

Appendix 7: Letter of Information

LETTER OF INFORMATION



Ontario Health is conducting a review of **pelvic floor muscle training for pelvic organ prolapse, stress urinary incontinence, or fecal incontinence**. The purpose is to better understand how this technique can be publicly funded in Ontario. An important part of this review involves gathering perspectives of patients and caregivers of those who have been diagnosed with pelvic organ prolapse, stress urinary incontinence, or fecal incontinence and who may or may not have used pelvic floor muscle training.

WHAT DO YOU NEED FROM ME

- ✓ Willingness to share your story
- ✓ 30-40 minutes of your time for a phone interview
- ✓ Permission to audio- (not video-) record the interview

WHAT YOUR PARTICIPATION INVOLVES

If you agree to share your experiences, you will be asked to have an interview with Ontario Health (OH) staff. OH staff will contact interested participants by collecting contact information (i.e., email address and/or phone number) to set up an interview. The interview will last about 30-40 minutes. It will be held over the telephone. With your permission, the interview will be audio-taped. The interviewer will ask you questions about you or your loved one's condition and your perspectives about treatment options in Ontario. Participation is voluntary. You may refuse to participate, refuse to answer any questions or withdraw before or at any point during your interview. Withdrawal will in no way affect the care you receive.

CONFIDENTIALITY

All information you share will be kept confidential and your privacy will be protected except as required by law. The results of this review will be published, however no identifying information will be released or published. Any records containing information from your interview will be stored securely until project completion. After completion of the project, the records will be destroyed. If you are sending us personal information by email, please be aware that electronic communication is not always secure and can be vulnerable to interception.

Ontario Health is designated an "institution" by the *Freedom of Information and Protection of Privacy Act* (FIPPA) and is collecting your personal information pursuant to FIPPA and the *Connecting Care Act, 2019* to support the Health Technology Assessment Program. If you have any questions regarding Ontario Health's collection and use of personal information for the purposes of this program, please contact Team Lead, Jigna Mistry noted below.

RISKS TO PARTICIPATION

There are no known physical risks to participating. Some participants may experience discomfort or anxiety after speaking about their experience.

IF YOU ARE INTERESTED, PLEASE CONTACT US:

Appendix 8: Interview Guide

PFMT Interview Guide

Lived- Experience

What is the impact of POP/SUI/FI and its progression on quality of life?

(Loss of independence?)

Impact on loved ones/caregivers, work, etc.?

Therapies

What current therapies/treatments are used and their impact?

Cost of therapies (example, PFMT)- covered by insurance vs out of pocket

Is accessibility to therapies/treatments an issue (are you able to take advantage of all potential therapies?)

Expectations of current therapies?

PFMT

Information surrounding PFMT for POP/SUI/FI?

Decision-making

PFMT Impact

Result, impact, change in quality of life (if applicable)

References

- (1) National Institute for Health and Care Excellence (NICE). Pelvic floor dysfunction: prevention and non surgical management: [M] pelvic floor muscle training for the management of symptoms. London: NICE; 2021.
- (2) Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Neurourol Urodyn*. 2010;29(4):4-20.
- (3) Al-Shaikh G, Syed S, Osman S, Bogis A, Al-Badr A. Pessary use in stress urinary incontinence: a review of advantages, complications, patient satisfaction, and quality of life. *Int J Womens Health*. 2018;10:195-201.
- (4) Frequently asked questions [Internet]. Markham (ON): Canadian Continence Foundation; c2024 [cited 2023 Apr 6]. Available from: <http://www.canadiancontinence.ca/EN/frequently-asked-questions.php>
- (5) Hage-Fransen MAH, Wiezer M, Otto A, Wieffer-Platvoet MS, Slotman MH, Nijhuis-van der Sanden MWG, et al. Pregnancy- and obstetric-related risk factors for urinary incontinence, fecal incontinence, or pelvic organ prolapse later in life: a systematic review and meta-analysis. *Acta Obstet Gynecol Scand*. 2021;100(3):373-82.
- (6) Mayo Clinic. Fecal incontinence [Internet]. Mayo Foundation for Medical Education and Research (MFMER); 2023 [cited 2023 Apr 6]. Available from: <https://www.mayoclinic.org/diseases-conditions/fecal-incontinence/symptoms-causes/syc-20351397>.
- (7) Bharucha AE, Zinsmeister AR, Schleck CD, Melton LJr. Bowel disturbances are the most important risk factors for late onset fecal incontinence: a population-based case-control study in women. *Gastroenterology*. 2010;139(5):1559-66.
- (8) Ditah I, Devaki P, Luma HN, Ditah C, Njei B, Jaiyeoba C, et al. Prevalence, trends, and risk factors for fecal incontinence in United States adults, 2005-2010. *Clin Gastroenterol Hepatol*. 2014;12(4):636-43.
- (9) Barber MD. Pelvic organ prolapse. *BMJ*. 2016;354:i3853.
- (10) Vergeldt TF, Weemhoff M, IntHout J, Kluivers KB. Risk factors for pelvic organ prolapse and its recurrence: a systematic review. *Int Urogynecol J*. 2015;26(11):1559-73.
- (11) Schulten SFM, Claas-Quax MJ, Weemhoff M, van Eijndhoven HW, van Leijsen SA, Vergeldt TF, et al. Risk factors for primary pelvic organ prolapse and prolapse recurrence: an updated systematic review and meta-analysis. *Am J Obstet Gynecol*. 2022;227(2):192-208.
- (12) Baessler K, Christmann-Schmid C, Maher C, Haya N, Crawford TJ, Brown J. Surgery for women with pelvic organ prolapse with or without stress urinary incontinence. *Cochrane Database Syst Rev*. 2018(8):CD013108.
- (13) National Institute of Diabetes and Digestive and Kidney Diseases. Rectal prolapse [Internet]. Bethesda (MD): National Institutes of Health, U.S. Department of Health and Human Services; c2019 [updated Aug 2019; cited 2024 Apr 26]. Available from: <https://www.niddk.nih.gov/health-information/digestive-diseases/anatomic-problems-lower-gi-tract/rectal-prolapse>
- (14) Scott KM. Pelvic floor rehabilitation in the treatment of fecal incontinence. *Clin Colon Rectal Surg*. 2014;27:99–105.
- (15) Gray M. Optimal management of incontinence-associated dermatitis in the elderly. *Am J Clin Dermatol*. 2010;11(3):201-10.

- (16) Akter F, Gartoulla P, Oldroyd J, Islam RM. Prevalence of, and risk factors for, symptomatic pelvic organ prolapse in Rural Bangladesh: a cross-sectional survey study. *Int Urogynecol J*. 2016;27(11):1753-9.
- (17) Reynolds WS, Dmochowski RR, Penson DF. Epidemiology of stress urinary incontinence in women. *Curr Urol Rep*. 2011;12(5):370-6.
- (18) Gacci M, De Nunzio C, Sakalis V, Rieken M, Cornu JN, Gravas S. Latest evidence on post-prostatectomy urinary incontinence. *J Clin Med*. 2023;12:1190.
- (19) Zorn KC, Gofrit ON, Orvieto MA, Mikhail AA, Zagaja GP, Shalhav AL. Robotic-assisted laparoscopic prostatectomy: functional and pathologic outcomes with interfascial nerve preservation. *Eur Urol*. 2007;51(3):755-62.
- (20) Patel VR, Thaly R, Shah K. Robotic radical prostatectomy: outcomes of 500 cases. *BJU Int*. 2007;99(5):1109-12.
- (21) Borin JF, Skarecky DW, Narula N, Ahlering TE. Impact of urethral stump length on continence and positive surgical margins in robot-assisted laparoscopic prostatectomy. *Urology*. 2007;70(1):173-7.
- (22) Menon M, Shrivastava A, Kaul S, Badani KK, Fumo M, Bhandari M, et al. Vattikuti Institute prostatectomy: contemporary technique and analysis of results. *Eur Urol*. 2007;51(3):648-57.
- (23) Whitehead WE, Borrud L, Goode PS, Meikle S, Mueller ER, Tuteja A, et al. Fecal incontinence in US adults: epidemiology and risk factors. *Gastroenterology*. 2009;137(2):512-7, 7.
- (24) Wu JM, Matthews CA, Vaughan CP, Markland AD. Urinary, fecal, and dual incontinence in older U.S. Adults. *J Am Geriatr Soc*. 2015;63(5):947-53.
- (25) Bureau M, Carlson KV. Pelvic organ prolapse: a primer for urologists. *Can Urol Assoc J*. 2017;11(6):S125-S30.
- (26) Bordman R, Telner D, Jackson B, Little D. Step-by-step approach to managing pelvic organ prolapse: information for physicians. *Can Fam Physician*. 2007;53(3):485-7.
- (27) Kow N, Goldman HB, Ridgeway B. Management options for women with uterine prolapse interested in uterine preservation. *Curr Urol Rep*. 2013;14(5):395-402.
- (28) Nygaard I, Barber MD, Burgio KL, Kenton K, Meikle S, Schaffer J. Prevalence of symptomatic pelvic floor disorders in US women. *JAMA*. 2008;300(11):1311-6.
- (29) Kairaluoma MV, Kellokumpu IH. Epidemiologic aspects of complete rectal prolapse. *Scand J Surg*. 2005;94(3):207-10.
- (30) Ontario Health. Vaginal pessaries for pelvic organ prolapse or stress urinary incontinence: a health technology assessment. *Ont Health Technol Assess Ser*. 2021;21(3):1-155.
- (31) Dufour S, Wu M. No. 397 - conservative care of urinary incontinence in women. *J Obstet Gynaecol Can*. 2020;42(4):510-22.
- (32) Harvey MA, Lemieux MC, Robert M, Schulz JA. Guideline no. 411: vaginal pessary use. *J Obstet Gynaecol Can*. 2021;43(2):255-66.e1.
- (33) Bettez M, Tu le M, Carlson K, Corcos J, Gajewski J, Jolivet M, et al. 2012 update: guidelines for adult urinary incontinence collaborative consensus document for the canadian urological association. *Can Urol Assoc J*. 2012;6(5):354-63.
- (34) Johnson EE, Mamoulakis C, Stoniute A, Omar MI, Sinha S. Conservative interventions for managing urinary incontinence after prostate surgery. *Cochrane Database Syst Rev*. 2023;4(4):CD014799.
- (35) Assmann SL, Keszthelyi D, Kleijnen J, Anastasiou F, Bradshaw E, Brannigan AE, et al. Guideline for the diagnosis and treatment of faecal Incontinence-a UEG/ESCP/ESNM/ESPCG collaboration [published correction appears in *United European Gastroenterol J*. 2022 Jul;10(6):606-607]. *United European Gastroenterol J*. 2022;10(3):251-86.

- (36) Bordeianou L, Paquette I, Johnson E, Holubar SD, Gaertner W, Feingold DL. Clinical practice guidelines for the treatment of rectal prolapse. *Dis Colon Rectum*. 2017;60(11):1121-31.
- (37) Frawley HC, Dean SG, Slade SC, Hay-Smith EJC. Is pelvic-floor muscle training a physical therapy or a behavioral therapy? A call to name and report the physical, cognitive, and behavioral elements. *Phys Ther*. 2017;97(4):425-37.
- (38) Ontario Physiotherapy Association. Access and payment [Internet]. 2023 [cited 2023 Sept 19]. Available from: <https://opa.on.ca/about-physiotherapy/access-payment/>
- (39) Government of Ontario. Physiotherapy clinics (government-funded) [Internet]. 2023 [cited 2023 Apr 6]. Available from: <https://www.ontario.ca/page/physiotherapy-clinics-government-funded>
- (40) Canadian Physiotherapy Association. Physiotherapy in Canada: payment and referral [Internet]. 2023 [cited 2023 Apr 6]. Available from: <https://physiotherapy.ca/advocacy/about-physiotherapy-in-canada/physiotherapy-in-canada/>
- (41) Institut national d'excellence en santé et en services sociaux. La rééducation périnéale et pelvienne pour la prévention et le traitement des dysfonctions du plancher pelvien volet 1 – incontinence urinaire. 2023.
- (42) Institut national d'excellence en santé et en services sociaux. La rééducation périnéale et pelvienne pour la prévention et le traitement des dysfonctions du plancher pelvien – volet 2 – dysfonction anorectale, prolapsus des organes pelviens et douleurs périnéales chez la femme. Québec (QC): 2023.
- (43) Cardozo L, Rovner E, Wagg A, Wein A, Abrams P, editors. *Incontinence*. 7 ed. Bristol (UK): International Continence Society; 2023.
- (44) American Urology Association. Incontinence after prostate treatment: AUA/SUFU guideline [Internet]. 2019 [cited 2023 Oct 6]. Available from: <https://www.auanet.org/guidelines-and-quality/guidelines/incontinence-after-prostate-treatment#x14381>
- (45) Dufour S, Clancy A, Wu M. Technical update no. 433: ehealth solutions for urinary incontinence among women. *J Obstet Gynaecol Can*. 2023;45(2):150-9.e1.
- (46) National Institute for Health and Care Excellence. Pelvic floor dysfunction: prevention and non-surgical management: [N] physical devices for the management of pelvic floor dysfunction London: NICE; 2021.
- (47) Forte ML, Andrade KE, Butler M, Lowry AC, Bliss DZ, Slavin JL, et al. Treatments for fecal incontinence. Comparative effectiveness review No. 165. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2012-00016-I.) AHRQ Publication No. 15(16)-EHC037-EF. Rockville, MD: Agency for Healthcare Research and Quality; 2016.
- (48) Stewart F, Fraser C, Robertson C, Avenell A, Archibald D, Douglas F, et al. Are men difficult to find? Identifying male-specific studies in MEDLINE and Embase. *Syst Rev*. 2014;3:78.
- (49) Parker RMN, Wanner A, Foster M, Lackey M, editors. Design and validation of a search filter for LGBTQ+ populations. Proceedings of the 25th Cochrane Colloquium; 2018; Edinburgh (UK): Cochrane Database of Systematic Reviews.
- (50) McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS peer review of electronic search strategies: 2015 guideline statement. *J Clin Epidemiol*. 2016;75:40-6.
- (51) Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *Journal of Clinical Epidemiology* [Internet]. 2021 [cited 2021 May 27]; 134: 178-89. Available from: <https://www.sciencedirect.com/science/article/pii/S0895435621000731>
- (52) Evidence for equity: PROGRESS-Plus [Internet]. London: Cochrane Collaboration; c2020 [cited 2023 Oct 6]. Available from: <https://methods.cochrane.org/equity/projects/evidence-equity/progress-plus>

- (53) Higgins JP, Thompson SG, Spiegelhalter DJ. A re-evaluation of random-effects meta-analysis. *J R Stat Soc Ser A Stat Soc.* 2009 Jan;172(1):137-59.
- (54) Whiting P, Savović J, Higgins JP, Caldwell DM, Reeves BC, Shea B. ROBIS: a new tool to assess risk of bias in systematic reviews was developed. *J Clin Epidemiol.* 2016;69:225-34.
- (55) Sterne JA, Savovic J, Page MJ, Elbers RG, Blencowe NS, Boutron I. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ.* 2019;366(i4898).
- (56) Schünemann H, Brožek J, Guyatt G, Oxman A, editors. *GRADE handbook.* Hamilton (ON): Grade Working Group; 2013.
- (57) Sahin UK, Acaroz S, Cirakoglu A, Benli E, Akbayrak T. Effects of external electrical stimulation added to pelvic floor muscle training in women with stress urinary incontinence: a randomized controlled study. *Neurourol Urodyn.* 2022;41(8):1781-92.
- (58) Dudoniene V, Kirklyte I, Zlibinaite L, Jerez-Roig J, Rutkauskaite R. Pelvic floor muscle training versus functional magnetic stimulation for stress urinary incontinence in women: a randomized controlled trial. *J Clin Med.* 2023;12(9):27.
- (59) Dumoulin C, Cacciari LP, Hay-Smith EJC. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev.* 2018;10(10):CD005654.
- (60) Imamura M, Abrams P, Bain C, Buckley B, Cardozo L, Cody J, et al. Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. *Health Technol Assess.* 2010;14(40):1-188, iii-iv.
- (61) Richter HE, Burgio KL, Brubaker L, Nygaard IE, Ye W, Weidner A. Continence pessary compared with behavioral therapy or combined therapy for stress incontinence: a randomized controlled trial. *Obstet Gynecol.* 2010;115(3):609-17.
- (62) Kenton K, Barber M, Wang L, Hsu Y, Rahn D, Whitcomb E. Pelvic floor symptoms improve similarly after pessary and behavioral treatment for stress incontinence. *Female Pelvic Med Reconstr Surg.* 2012;18(2):118-21.
- (63) Stewart F, Berghmans B, Bø K, Glazener CM. Electrical stimulation with non-implanted devices for stress urinary incontinence in women. *Cochrane Database Syst Rev.* 2017;12(12):CD012390.
- (64) Herbison GP, Dean N. Weighted vaginal cones for urinary incontinence. *Cochrane Database Syst Rev.* 2013(7):CD002114.
- (65) Moroni RM, Magnani PS, Haddad JM, de Castro RA, Brito LG. Conservative treatment of stress urinary incontinence: A systematic review with meta-analysis of randomized controlled trials. *Rev Bras Ginecol Obstet.* 2016;38(2):97-111.
- (66) Woodley SJ, Lawrenson P, Boyle R, Cody JD, Mørkved S, Kernohan A, et al. Pelvic floor muscle training for preventing and treating urinary and faecal incontinence in antenatal and postnatal women. *Cochrane Database Syst Rev.* 2020;5:CD007471.
- (67) Liang J, Fang S, Li W, Zhao L, Sun X, Xie Z. Comparative effectiveness of nonsurgical treatment for stress urinary incontinence in adult women : a systematic review and network meta-analysis of randomized controlled trials. *Int J Clin Exp Med.* 2018;11(10):10397-416.
- (68) Filocamo MT, Li Marzi V, Del Popolo G, Cecconi F, Marzocco M, Tosto A, et al. Effectiveness of early pelvic floor rehabilitation treatment for post-prostatectomy incontinence. *Eur Urol.* 2005;48(5):734-8.
- (69) Laurienzo CE, Magnabosco WJ, Jabur F, Faria EF, Gameiro MO, Sarri AJ, et al. Pelvic floor muscle training and electrical stimulation as rehabilitation after radical prostatectomy: a randomized controlled trial. *J Phys Ther Sci.* 2018;30(6):825-31.
- (70) Manassero F, Traversi C, Ales V, Pistolesi D, Panicucci E, Valent F, et al. Contribution of early intensive prolonged pelvic floor exercises on urinary continence recovery after bladder neck-

- sparing radical prostatectomy: results of a prospective controlled randomized trial. *Neurourol Urodyn*. 2007;26(7):985-9.
- (71) Van Kampen M, De Weerd W, Van Poppel H, De Ridder D, Feys H, Baert L. Effect of pelvic-floor re-education on duration and degree of incontinence after radical prostatectomy: a randomised controlled trial. *Lancet*. 2000;355(9198):98-102.
- (72) Moore KN, Valiquette L, Chetner MP, Byrniak S, Herbison GP. Return to continence after radical retropubic prostatectomy: a randomized trial of verbal and written instructions versus therapist-directed pelvic floor muscle therapy. *Urology*. 2008;72(6):1280-6.
- (73) Sanchez-Salas R, Sivaraman A, Tourinho-Barbosa R, Pasquali C, Candela L, Marra G. The IMPROVE trial: surgical technique remains the most important factor associated with recovery of urinary continence after radical prostatectomy (Abstract LBA02-08). *J Urol*. 2021;206:e1178.
- (74) Moore KN, Griffiths D, Hughton A. Urinary incontinence after radical prostatectomy: a randomized controlled trial comparing pelvic muscle exercises with or without electrical stimulation. *BJU Int*. 1999;83(1):57-65.
- (75) Strojek K, Weber-Rajek M, Strączyńska A, Piekorz Z, Pilarska B, Jarzowski P, et al. Randomized-controlled trial examining the effect of pelvic floor muscle training in the treatment of stress urinary incontinence in men after a laparoscopic radical prostatectomy pilot study. *J Clin Med*. 2021;10(13):2946.
- (76) Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence.
- (77) Damon H, Siproudhis L, Faucheron JL, Piche T, Abramowitz L, Eléouet M, et al. Perineal retraining improves conservative treatment for faecal incontinence: a multicentre randomized study. *Dig Liver Dis*. 2014;46(3):237-42.
- (78) Hagen S, Stark D. Conservative prevention and management of pelvic organ prolapse in women. *Cochran Database Syst Rev*. 2011(12):CD003882.
- (79) Nyhus MØ, Mathew S, Salvesen Ø, Salvesen KÅ, Stafne S, Volløyhaug I. Effect of preoperative pelvic floor muscle training on pelvic floor muscle contraction and symptomatic and anatomical pelvic organ prolapse after surgery: randomized controlled trial. *Ultrasound Obstet Gynecol*. 2020;56(1):28-36.
- (80) Liang Y, Li X, Wang J, Liu Y, Yang Y, Dong M. Effect of pelvic floor muscle training on improving prolapse-related symptoms after surgery. *J Nurse P*. 2019;15:600–5.
- (81) Ge J, Wei XJ, Zhang HZ, Fang GY. Pelvic floor muscle training in the treatment of pelvic organ prolapse: a meta-analysis of randomized controlled trials. *Actas Urol Esp (Engl Ed)*. 2021;45(1):73-82.
- (82) Panman CM, Wiegersma M, Kollen BJ, Berger MY, Lisman-van Leeuwen Y, Vermeulen KM, et al. Effectiveness and cost-effectiveness of pessary treatment compared with pelvic floor muscle training in older women with pelvic organ prolapse: 2-year follow-up of a randomized controlled trial in primary care. *Menopause*. 2016;23(12):1307-18.
- (83) National Institute for Health and Care Excellence. Process and methods guides. Appendix I: Quality appraisal checklist—economic evaluations [Internet]. London: NICE; 2012 [cited 2016 Jan]. Available from: <https://www.nice.org.uk/process/pmg4/chapter/appendix-i-quality-appraisal-checklist-economic-evaluations>
- (84) National Institute for Health and Care Excellence. Pelvic floor dysfunction: prevention and non-surgical management. London: NICE; 2021.
- (85) Chang OH, Cadish LA, Kailasam A, Ridgeway BM, Shepherd JP. Impact of the availability of midurethral slings on treatment strategies for stress urinary incontinence: a cost-effectiveness analysis. *BJOG*. 2022;129(3):500-8.

- (86) Simpson AN, Garbens A, Dossa F, Coyte PC, Baxter NN, McDermott CD. A cost-utility analysis of nonsurgical treatments for stress urinary incontinence in women. *Female Pelvic Med Reconstr Surg*. 2019;25(1):49-55.
- (87) Panman C, Wiegersma M, Kollen BJ, Berger MY, Lisman-Van Leeuwen Y, Vermeulen KM, et al. Two-year effects and cost-effectiveness of pelvic floor muscle training in mild pelvic organ prolapse: a randomised controlled trial in primary care. *BJOG*. 2017;124(3):511-20.
- (88) Glazener C, Boachie C, Buckley B, Cochran C, Dorey G, Grant A, et al. Conservative treatment for urinary incontinence in men after prostate surgery (MAPS): two parallel randomised controlled trials. *Health Technol Assess*. 2011;15(24):1-290, iii-iv.
- (89) Milsom I, Gyhagen M. The prevalence of urinary incontinence. *Climacteric*. 2019;22(3):217-22.
- (90) Puranda JL, da Silva DF, Edwards CM, Nagpal TS, Souza SCS, Semeniuk K, et al. Characteristics associated with pelvic floor disorders among female canadian armed forces members. *J Obstet Gynaecol Can*. 2023;45(9):646-54.
- (91) Shaw C, Cahill J, Wagg A. The current state of continence in Canada: a population representative epidemiological survey. *Can J Urol*. 2020;27(4):10300-5.
- (92) Scime NV, Hetherington E, Metcalfe A, Chaput KH, Dumanski SM, Seow CH, et al. Association between chronic conditions and urinary incontinence in females: a cross-sectional study using national survey data. *CMAJ Open*. 2022;10(2):E296-E303.
- (93) Kenne KA, Wendt L, Brooks Jackson J. Prevalence of pelvic floor disorders in adult women being seen in a primary care setting and associated risk factors. *Sci Rep*. 2022;12(1):9878.
- (94) Wu JM, Vaughan CP, Goode PS, Redden DT, Burgio KL, Richter HE, et al. Prevalence and trends of symptomatic pelvic floor disorders in U.S. women. *Obstet Gynecol*. 2014;123(1):141-8.
- (95) Markland AD, Goode PS, Redden DT, Borrud LG, Burgio KL. Prevalence of urinary incontinence in men: results from the National Health and Nutrition Examination Survey. *J Urol*. 2010;184(3):1022-7.
- (96) Patel UJ, Godecker AL, Giles DL, Brown HW. Updated prevalence of urinary incontinence in women: 2015-2018 national population-based survey data. *Female Pelvic Med Reconstr Surg*. 2022;28(4):181-7.
- (97) Statistics Canada. Population estimates on July 1st, by age and sex [Internet]. Ottawa (ON): Statistics Canada. c2023 [cited 2023 Aug 24]. Available from: <https://doi.org/10.25318/1710000501-eng>
- (98) Sutherland G, Dinh T. Understanding the gap: a pan-Canadian analysis of prescription drug insurance coverage.
- (99) Institut national d'excellence en santé et en services sociaux. La rééducation périnéale et pelvienne pour la prévention et le traitement des dysfonctions du plancher pelvien volet 1 – incontinence urinaire. Annexes complémentaires. 2022.
- (100) Ministry of Health and Long-Term Care. Ontario community physiotherapy clinic program: patient information [Internet]. 2021 [Available from: <https://www.ontario.ca/page/physiotherapy-clinics-government-funded>
- (101) Cacciari LP, Kouakou CR, Poder TG, Vale L, Morin M, Mayrand MH, et al. Group-based pelvic floor muscle training is a more cost-effective approach to treat urinary incontinence in older women: economic analysis of a randomised trial. *J Physiother*. 2022;68(3):191-6.
- (102) Statistics Canada. Consumer price index: Tables 18-10-0004-01, 18-10-0004-02, and 18-10-0005-01 [Internet]. Ottawa (ON): Statistics Canada. c2023 [cited 2023 Aug 25]. Available from: <https://www.statcan.gc.ca/en/subjects-start/prices-and-price-indexes/consumer-price-indexes>
- (103) Canada Go. Wages: physiotherapist in Canada, hourly wages by community/area [Internet]. 2023 [Available from: <https://www.jobbank.gc.ca/marketreport/wages-occupation/18214/ca>

- (104) Toronto Physiotherapy Clinics. Physiotherapy treatment rates [Internet]. 2023 [Available from: <https://torontophysiotherapy.ca/fees/pricing-list/>]
- (105) Trofimenko V, Myers JB, Brant WO. Post-prostatectomy incontinence: how common and bothersome is it really? *Sex Med Rev.* 2017;5(4):536-43.
- (106) Barham L. Public and patient involvement at the UK National Institute for Health and Clinical Excellence. *The patient.* 2011;4(1):1-10.
- (107) Messina J, Grainger DL. A pilot study to identify areas for further improvements in patient and public involvement in health technology assessments for medicines. *The patient.* 2012;5(3):199-211.
- (108) Ontario Health Technology Advisory Committee Public Engagement Subcommittee. Public engagement for health technology assessment at Health Quality Ontario—final report from the Ontario Health Technology Advisory Committee Public Engagement Subcommittee [Internet]. Toronto (ON): Queen's Printer for Ontario; 2015 Apr [cited 2018 Apr 30]. Available from: <http://www.hqontario.ca/Portals/0/documents/evidence/special-reports/report-subcommittee-20150407-en.pdf>
- (109) Health Technology Assessment Unit. Open radical prostatectomy, laparoscopic radical prostatectomy, and robotic assisted radical prostatectomy. University of Calgary; 2020.
- (110) Canada's Drug and Health Technology Agency. Prostatectomy for people with prostate cancer: a rapid qualitative review. Ottawa (ON): CADTH; 2019. Contract No.: RC1209-000.
- (111) Karantanis E, Parsons M, Blackwell A, Robinson D, Cardozo L, Moore KH. Women's treatment preferences for stress urinary incontinence: physiotherapy or surgery. *ANZCJ.* 2014;20(2):34-42.
- (112) Limbutara W, Bunyavejchevin S, Ruanphoo P, Chiengthong K. Patient-reported goal achievements after pelvic floor muscle training versus pessary in women with pelvic organ prolapse. A randomised controlled trial. *J Obstet Gynaecol.* 2023;43(1):2181061.
- (113) Health Canada. Surgical mesh - complications associated with transvaginal implantation for the treatment of stress urinary incontinence and pelvic organ prolapse - notice to hospitals [Internet]. Government of Canada; 2014 [cited 2023]. Available from: <https://recalls-rappels.canada.ca/en/alert-recall/surgical-mesh-complications-associated-transvaginal-implantation-treatment-stress>
- (114) Kvale S. *Interviews: an introduction to qualitative research interviewing.* Thousand Oaks (CA): Sage; 1996.
- (115) Kuzel AJ. Sampling in qualitative inquiry. In: Miller WL, Crabtree BF, editors. *Doing qualitative research.* Thousand Oaks (CA): Sage; 1999. p. 33–45.
- (116) Morse J. Emerging from the data: cognitive processes of analysis in qualitative research. In: Morse J, editor. *Critical issues in qualitative research methods.* Thousand Oaks (CA): Sage; 1994. p. 23-41.
- (117) Patton MQ. *Qualitative research and evaluation methods.* 3rd ed. Thousand Oaks (CA): Sage; 2002.
- (118) Strauss AL, Corbin JM. *Basics of qualitative research: techniques and procedures of developing a grounded theory.* 2nd ed. Thousand Oaks (CA): Sage; 1998.
- (119) Health Technology Assessment International. Introduction to health technology assessment [Internet]. Edmonton (AB): Health Technology Assessment International; 2015 [cited 2018 Apr 30]. Available from: http://www.htai.org/fileadmin/HTAi_Files/ISG/PatientInvolvement/v2_files/Resource/PCISG-Resource-Intro to HTA KFacey Jun13.pdf
- (120) Strauss AL, Corbin JM. Grounded theory research: procedures, canons, and evaluative criteria. *Qual Sociol.* 1990;13(1):3-21.

- (121) Strauss AL, Corbin JM. Grounded theory methodology: an overview. In: Denzin NK, Lincoln YS, editors. Handbook of qualitative research. Thousand Oaks (CA): Sage; 1994. p. 273-85.
- (122) NVivo qualitative data analysis software. QSR International. Doncaster, Victoria (Australia). Available at: <https://www.qsrinternational.com/nvivo/home>.
- (123) Ontario Health's equity, inclusion, diversity and anti-racism framework [Internet]. Toronto (ON): Ontario Health; 2022 [cited 2023 Mar 22]. Available from: <https://www.ontariohealth.ca/sites/ontariohealth/files/2020-12/Equity%20Framework.pdf>
- (124) World Health Organization. Social determinants of health: key concepts [Internet]. Geneva: The Organization; 2013 May 7 [cited 2022 Mar 22]. Available from: <https://www.who.int/news-room/questions-and-answers/item/social-determinants-of-health-key-concepts>

About Us

We are an agency created by the Government of Ontario to connect, coordinate, and modernize our province's health care system. We work with partners, providers, and patients to make the health system more efficient so everyone in Ontario has an opportunity for better health and well-being.

For more information about Ontario Health, visit [OntarioHealth.ca](https://ontariohealth.ca).

Equity, Inclusion, Diversity and Anti-Racism

Ontario Health is committed to advancing equity, inclusion and diversity and addressing racism in the health care system. As part of this work, Ontario Health has developed an [Equity, Inclusion, Diversity and Anti-Racism Framework](#), which builds on existing legislated commitments and relationships and recognizes the need for an intersectional approach.

Unlike the notion of equality, equity is not about sameness of treatment. It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

ontariohealth.ca/equity-inclusion-diversity-and-anti-racism

[About the Ontario Health Technology Advisory Committee](#)

[How to Obtain Reports From the Ontario Health Technology Assessment Series](#)

[Disclaimer](#)

Ontario Health
500–525 University Avenue
Toronto, Ontario
M5G 2L3
Toll Free: 1-877-280-8538
TTY: 1-800-855-0511
Email: OH-HQO_HTA@OntarioHealth.ca
hqontario.ca

ISSN 1915-7398 (online)
ISBN 978-1-4868-8186-4 (PDF)

© King’s Printer for Ontario, 2024

The copyright for all Ontario Health publications is owned by the [King’s Printer for Ontario](#). Materials may be reproduced for commercial purposes only under a licence from the King’s Printer. For further information or to request a licence to reproduce content, please contact:

Senior Copyright Advisor
Publications Ontario
416-326-5153
Copyright@Ontario.ca

Need this information in an accessible format?
1-877-280-8538, TTY 1-800-855-0511, info@OntarioHealth.ca
Document disponible en français en contactant info@OntarioHealth.ca

