Faecal Incontinence in North Queensland

Lynne Marion Bartlett

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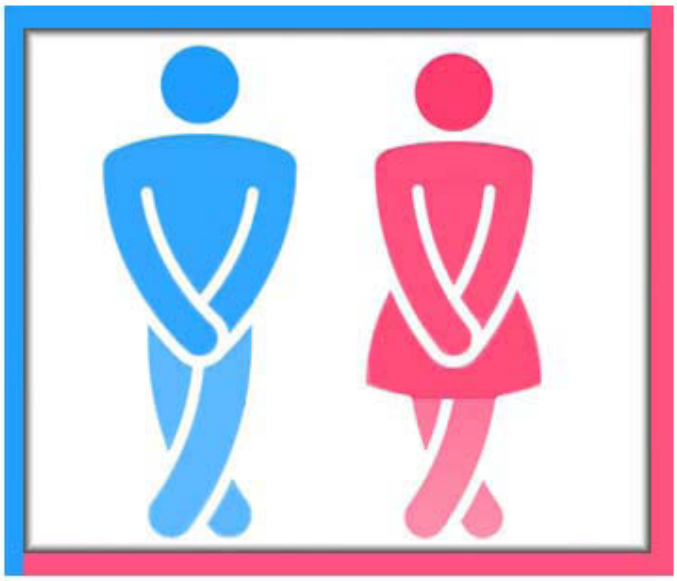

A thesis submitted to the Faculty of Medicine, Health and Molecular Sciences, James Cook University, in fulfillment of the requirements for the degree of Doctor of Public Health

TOWNSVILLE, MARCH 2014

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Lynne Bartlett 20 March 2014

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Information derived from the published or unpublished work of others has been acknowledged in the text and a list of references is given.

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Lynne Bartlett 20 March 2014

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Declaration on ethics

The research presented and reported in this thesis was conducted within the guidelines for research ethics outlined in the National Statement on Ethics Conduct in Research Involving Humans (1999), the Joint NHMRC/AVCC Statement and Guidelines on Research Practice (1997), the James Cook University Policy on Experimentation Ethics, Standard Practices and Guidelines (2001), and the James Cook University Statement and Guidelines on Research Practice (2001). Specific ethics approval details are provided in each publication.

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Lynne Bartlett 20 March 2014

Summary

Faecal incontinence, the uncontrolled loss of liquid or solid stool, can have a profound, negative effect on a person's quality of life, including their social and economic status. Up to 15% of metropolitan community residing adults and over 50% per cent of those in residential aged care suffer with the condition. The prevalence of faecal incontinence rises with age and by 2047 one quarter of the Australian population will be over 65 raising serious concerns with regard to continence management.

The overall aim of the research contained in this thesis is to expand the evidence base of faecal incontinence in regional and rural Australia, specifically conducting epidemiological and clinical research in order to direct health policy and practice.

This thesis describes six studies that explored several important areas of clinical and public health relevance: disclosure of faecal incontinence - comparative study on two tools in a clinical setting; prevalence of faecal incontinence in the population - cross-sectional postal survey of northern Queensland community residing adults; quality of life of patients with faecal incontinence - survey of clinical patients; two randomised clinical trials investigating anorectal biofeedback – a comparative study of exercise regimen and another comparing the standard anorectal biofeedback program with / without supplementary self-managed home biofeedback; and the impact of relaxation breathing on anal pressure - an observational study of biofeedback patients.

The overall aim of this body of work was to expand the evidence base of faecal incontinence in regional and rural Australia. The research setting was Northern Queensland and the people with faecal incontinence who live and work in this regional, rural and remote part of Australia.

Disclosure of faecal incontinence

Adult patients attending the urogynaecology and colorectal outpatient clinics at the Townsville Hospital in 2003/4 were invited to complete a self-administered faecal incontinence questionnaire and answer faecal incontinence questions asked by their treating doctor. There was a substantial difference in disclosure using the two measurement instruments. The discordance was predominantly due to issues of definition, understanding, terminology and embarrassment. Once adjusted for the measurement differences, the prevalence was 26.0% (95% CI, 20.9%–

31.1%), which confirmed findings from an earlier survey in a similar population. Other findings included:

- Routine patient consultations with general practitioners should include faecal incontinence questions for those with risk factors
- A more specific definition which excludes historical data and isolated instances of diarrhoea due to acute illness is desirable
- A measurement instrument suitable for population surveys should contain simple language and acknowledge issues of embarrassment.

Prevalence

Faecal incontinence was defined as accidental leakage of solid or liquid stool in the previous twelve months which was not caused by a virus, medication or contaminated food. A bowel habit survey was mailed to 3620 private listings compiled from the 2006/7 Cairns and Townsville telephone directories. A response rate of 48.1% from 1523 responses was achieved. This region is particularly mobile which may explain the low response rate. Of the northern Queensland adult community members surveyed 12.7% reported faecal incontinence. This rate increased with age for men; overall there were no gender or locality differences. When soiling with flatus and urgency were included, stool related accidental bowel leakage was substantially higher at 18.2%. Using the broader definition of accidental stool leakage that did not exclude faecal incontinence resulting from an acute illness, the prevalence was 28.1%, the highest reported in Australia.

Quality of life

The quality of life of more than 22% of study participants who attended the urogynaecology and colorectal outpatient clinics at the Townsville Hospital in 2003 and 2004 for matters other than faecal incontinence was severely affected by faecal incontinence. Colorectal clinic participants had poorer quality of life than those attending the urogynaecology clinic. The negative impact on participants' lives worsened with the loss of both solid and liquid stool and increased frequency and quantity of soiling.

Biofeedback therapy

Anorectal biofeedback is a conservative therapy for patients with mild to moderate faecal incontinence who have not responded to general practitioner prescribed advice. The aim of

anorectal biofeedback is to enable patients to identify, contract, and relax the anal sphincter and pelvic floor muscles which support the abdominal contents against gravity and help maintain urinary and faecal continence. A balloon is positioned in the rectal vault and inflated until the patient registers its presence. A catheter with a pressure transducer placed in the patient's anal canal measures pelvic floor muscle activity converting anal pressure readings to a display screen for immediate visual feedback.

Exercises:

A randomised study compared an untested exercise regimen of sustained plus rapid exercises with the standard exercise regimen of sustained exercises at the Townsville Hospital Anorectal Physiology Clinic. This study was in response to demands for randomised clinical trials investigating anal sphincter and pelvic floor exercises. Seventy-two participants attended clinic sessions once weekly for four weeks followed by four weeks of home practice and a follow-up assessment session. A postal survey was conducted two years later. No significant differences were found between the two exercise groups at the beginning or at the end of the study or as a result of treatment in objective, quality of life, or faecal incontinence severity measures. Compliant participants had better outcomes than those who practiced fewer exercises. Eighty six per cent of participants reported improved continence and incontinence severity decreased significantly. Results were sustained two years later.

Location:

Regional participants lived a median distance of 8km from the clinic, while rural participants travelled up to 903km to attend clinic sessions. Risk factors for faecal incontinence were similar for rural and regional participants, although rural participants reported poorer general health and their symptoms affected their lifestyle more negatively. Initially improvement in rural participants' outcomes was marginally better than those of regional participants. However two years later, severity and quality of life continued to improve among regional participants, but rural participants had regressed to pre-treatment levels. An additional follow-up session with the biofeedback therapist, ongoing local support by continence advisors or a telephone helpline, newsletter, or webpage should be investigated for rural patients to help maintain similar long-term improvement in continence and quality of life to regional participants.

Bowel dysfunction following colorectal cancer surgery:

Up to 60% of patients experience bowel dysfunction following surgery, which is the usual treatment for colorectal cancer. Post-surgery bowel dysfunction symptoms include frequent bowel motions, urgency, excessive flatus, incomplete bowel evacuation, constipation and in 35-39% of Australian patients, faecal incontinence. Nineteen patients with post colorectal cancer surgery bowel dysfunction including faecal incontinence achieved significant symptom reduction as a result of biofeedback therapy. Patients' satisfaction was high and their subjective bowel control rating and quality of life improved. There was further improvement in the quality of life scores two years after the completion of treatment, which led to the conclusion that the holistic biofeedback program was successful in the short and medium term.

Practical strategies for treating post-surgery bowel dysfunction: Outlined is the holistic approach used in the Townsville Hospital biofeedback program for bowel dysfunction following colorectal surgery. Strategies described include assessment, education, support and assistance with coping, individualized dietary and fluid modifications, medications, and exercise methodology.

Treatment of post-surgery bowel dysfunction: Biofeedback-assisted pelvic floor muscle strength training; relaxation techniques; effective bowel evacuation; modification of rectal sensitivity; and anorectal coordination training to alleviate stool frequency and urgency is described for patients with bowel dysfunction following colorectal surgery.

Home biofeedback:

Participants were concerned about performing prescribed exercises correctly in the first biofeedback study, with many expressing a desire to have the clinic biofeedback equipment at home. While a home biofeedback study conducted in England failed to deliver better outcomes than standard treatment, 90 per cent of our study participants were willing to try such a device. A perineometer with an anal sensor and an internal memory, developed in Australia, enabled a home biofeedback study.

Seventy five participants (12 male, 48% rural), mean age 61.1 years consented to attend 3 weekly sessions, 4 weeks home practice and a follow-up assessment session. 36 patients (7 male) were randomized to the standard biofeedback protocol and 39 (5 male) to biofeedback protocol plus daily home use of a Peritron perineometer.

Continence and quality of life were significantly improved in the younger intervention participants compared with controls when results were stratified above and below the mean age. However, with the exception of Life style and Embarrassment scales, supplementary home biofeedback did not result in greater clinical improvement for the intervention group as a whole. Perineometer compliance was excellent and significant improvement in exercise technique and performance was seen over the course of the treatment. Most perineometer participants found it helped with the exercise program, providing feedback, reassurance, motivation, building confidence quickly and acting as an exercise reminder. Home use of a relatively inexpensive commercially available perineometer with an anal sensor was acceptable and well tolerated by participants. With demand for FI management likely to grow, a video treatment program incorporating existing biofeedback therapy components and perineometer use warrants further research.

Relaxation breathing

Diaphragmatic breathing elicits a relaxation response and is a successful technique in anxiety related disorders. All anorectal biofeedback study participants were taught relaxation breathing using computer assisted anorectal biofeedback. During relaxation breathing practice sessions a change in the anorectal pressure waves was observed in many patients with post-surgery bowel dysfunction. Pressure traces changed from wide amplitude waves to smaller amplitude, more regular wave patterns. Other incontinent patients with very low amplitude wave patterns prior to relaxation breathing training developed regular, gentle wave patterns. Relaxation breathing is a common treatment element in many anorectal biofeedback programs but its beneficial effect on patients with faecal incontinence and urgency had not previously been quantified. The variance of anal resting pressure for patients with faecal incontinence decreased during relaxation breathing and those patients with post-surgery bowel dysfunction showed a significantly greater reduction of variation in pressure wave amplitude than patients with FI due to other causes. Relaxation breathing promotes more regular internal anal sphincter pressure wave patterns and as a management technique it may aid in the reduction of incontinent episodes and faecal urgency.

Outcomes

This research has determined that there is a high level of previously undisclosed and untreated faecal incontinence in the northern Queensland community. The quality of life of those with the condition is severely affected. The anorectal biofeedback program investigated delivered

significant improvements in severity and quality of life for patients with faecal incontinence, including those with post-surgery bowel dysfunction. *This is important as more than a third of Australians who have colorectal cancer surgically excised are left with faecal incontinence.* Rural patients' incontinence relapsed post biofeedback treatment; thus, they require extended support. This has since been provided through telephone consultations. Home biofeedback was acceptable and well tolerated by participants. Following this research the biofeedback clinic has doubled its hours of operation, and employed a second therapist. Growth in demand for faecal incontinence management is anticipated due to aging populations, younger more assertive cohorts and increased colorectal cancer survival. This increase for treatment will justify further research into a video program incorporating home biofeedback targeting a broader reach of therapists and possibly patient self-management. To facilitate timely dissemination of evidence and to ensure that the work is of high quality, results have already been published in 9 peer reviewed papers and that these are used to form the body of the thesis.

Chapter overview:

Chapter 1: Introduction

This chapter describes the context of this research; discusses definitions of faecal incontinence; argues why people may fail to disclose the condition; summarises diagnoses, impact on quality of life and available treatments.

Chapter 2: Disclosure

In a study conducted in 2003 at the Townsville hospital urogynaecology and colorectal outpatient clinics, some participants disclosed faecal incontinence differently on two different survey instruments. This chapter replicated that study and examined the reasons for disclosure differences in a new group of patients.

2.1 Discordance between two survey tools

Bartlett L, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Techniques in Coloproctology*. 2007;11:251-7

Chapter 3: Prevalence

Australian faecal incontinence prevalence surveys have focussed on metropolitan community-dwelling adults. This chapter explores the prevalence of the condition in regional and rural centres.

3.1 Prevalence of faecal incontinence in northern Queensland

Bartlett L, Nowak M, Ho YH. Faecal incontinence in rural and regional northern Queensland community-dwelling adults. *Rural and Remote Health*. 2013;13:2563

Chapter 4: Quality of life

Faecal incontinence can be measured as present or absent, by severity and by the burden on a person's quality of life. The impact of faecal incontinence on quality of life of patients attending the Townsville Hospital colorectal and urogynaecology clinics, for reasons other than incontinence, was assessed in this chapter.

4.1 Impact of faecal incontinence on quality of life

Bartlett L, Nowak M, Ho YH. Impact of fecal incontinence on quality of life. World Journal of Gastroenterology. 2009;15:3276-82

Chapter 5: Biofeedback

Since 2002 an anorectal biofeedback program has been available at the Townsville hospital for patients with bowel problems refractory to standard general practitioner prescribed conservative medical and pelvic floor exercise treatment. This chapter investigates outcomes from the biofeedback program for patients with faecal incontinence.

5.1 Exercise regimens compared

Bartlett L, Sloots K, Nowak M, Ho Y-H . Biofeedback for fa ecal incontinence: a randomized control study comparing exercise regimen. *Diseases of the Colon and Rectum*. 2011;54:846-856.

5.2 Impact on rural and regional participants

Bartlett L, Sloots K , Nowak M, Ho YH. Biofeedback therapy for faecal incontinence: a rural and regional perspective. *Rural and Remote Health*. 2011;11:1630

5.3 Bowel dysfunction following colorectal cancer surgery

Bartlett L, S loots K, Nowak M, Ho YH . Biofeedback therapy for symptoms of bowel dysfunction following surgery for colorectal cancer. *Techniques in coloproctology*. 2011;15:319-326:

5.4 Practical strategies for treating post-surgery bowel dysfunction

Sloots K, Ba rtlett L. Prac tical strategies for tr eating postsurgical bowel dysfunction. *Journal of Wound, Ostomy, and Continence Nursing*. 2009;36:522-7

5.5 Treatment of post-surgery bowel dysfunction

Sloots K, Bartlett L, H o YH. Treatment of postsurgery bowel dysfunction: biofeedback therapy. *Journal of Wound, Ostomy, and Continence Nursing*. 2009;36:651-8

5.6 Supplementary home biofeedback for faecal incontinence

Bartlett L, Sloots K, Nowak M, Ho. Y. Sup plementary home biofeedback improves quality of life in younger patients with fecal incontinence. *Journal of Clinical Gastroenterology*, 2013 ***(In press)***

Chapter 6: Relaxation breathing

A rhythmic change in the anor ectal pressure waves was observed in many patients with post-surgery bowel dysfunction when they practiced relaxation breathing during anorectal biofeedback. The effect of relaxation breathing on anorectal function was investigated in this chapter.

6.1 Relaxation breathing in patients with faecal incontinence

Bartlett L, Sloots K, Nowak M, Ho Y-H. Impact of relaxation breathing on the internal anal sphincter in patients with fecal incontinence. The Australian and New Zealand Continence Journal. 2012;18:38-45

Chapter 7: Conclusion, outcomes and future research directions

This chapter gives the conclusions from the studies and proposes future research directions.

Preface and acknowledgements

The research studies included in this thesis involved a small number of co-in vestigators. Achievements from this work are directly related to the passion, energy and dedication of each of the people involved, particularly Kathryn Sloots.

My supervisors Dr Madeleine Nowak, Professors Richard Speare a nd Yik-Hong Ho have provided invaluable guidance, support, technical expertise and encouragement to me during this work.

Contributors and my role

		Study component / Contributor		Lynne Bartlett	Kathryn Sloots	Madeleine Nowak	Yik-Hong Ho
Chapter 2: Disclosure		Design	12.5%	75%	0%	0%	25%
		Funding	12.5%	50%	0%	0%	50%
		Ethics and permissions	12.5%	100%	0%	0%	0%
		Conducted study	12.5%	90%	10%	0%	0%
		Data entry and analysis	12.5%	100%	0%	0%	0%
		Drafted manuscript	12.5%	60%	0%	40%	0%
		Edited manuscript	12.5%	40%	0%	50%	10%
		Managed manuscript submission	12.5%	100%	0%	0%	0%
				76.9%	**1.3%**	**11.3%**	**10.6%**
Chapter 3: Prevalence		Design	12.5%	90%		5%	5%
		Funding	12.5%	85%		10%	5%
		Ethics and permissions	12.5%	100%		0%	0%
		Conducted study	12.5%	100%		0%	0%
		Data entry and analysis	12.5%	100%		0%	0%
		Drafted manuscript	12.5%	100%		0%	0%
		Edited manuscript	12.5%	40%		50%	10%
		Managed manuscript submission	12.5%	100%		0%	0%
				89.4%		**8.1%**	**2.5%**
Chapter 4: Quality of Life		Data entry and analysis	25.0%	100%		0%	0%
		Drafted manuscript	25.0%	100%		0%	0%
		Edited manuscript	25.0%	50%		40%	10%
		Managed manuscript submission	25.0%	100%		0%	0%
				87.5%		**10%**	**2.5%**
Chapter 5: Biofeedback	**1: Exercise regimens compared**	Design	12.5%	80%	10%	5%	5%
		Funding	12.5%	50%	0%	0%	50%
		Ethics and permissions	12.5%	100%	0%	0%	0%
		Conducted study	12.5%	40%	60%	0%	0%
		Data entry and analysis	12.5%	100%	0%	0%	0%
		Drafted manuscript	12.5%	100%	0%	0%	0%
		Edited manuscript	12.5%	40%	10%	45%	5%
		Managed manuscript submission	12.5%	100%	0%	0%	0%
				76.3%	**10.0%**	**6.3%**	**7.5%**
	2: Impact on rural and regional participants	Data entry and analysis	25.0%	100%	0%	0%	0%
		Drafted manuscript	25.0%	100%	0%	0%	0%
		Edited manuscript	25.0%	40%	10%	40%	10%
		Managed manuscript submission	25.0%	100%	0%	0%	0%
				85%	**2.5%**	**10%**	**2.5%**
	3: Post colorectal cancer surgery bowel dysfunction	Data entry and analysis	25.0%	100%	0%	0%	0%
		Drafted manuscript	25.0%	100%	0%	0%	0%
		Edited manuscript	25.0%	35%	20%	35%	10%
		Managed manuscript submission	25.0%	100%	0%	0%	0%
				83.7%	**5%**	**8.8%**	**2.5%**
	4: Practical Strategies	Drafted manuscript	33.3%	5%	95%		
		Edited manuscript	33.3%	25%	75%		
		Managed manuscript submission	33.3%	0%	100%		
				10.0%	**90.0%**		
	5: Treatment methodology	Drafted manuscript	33.3%	5%	95%		0%
		Edited manuscript	33.3%	30%	65%		10%
		Managed manuscript submission	33.3%	0%	100%		0%
				10.0%	**86.6%**		**3.3%**
	6: Home biofeedback	Design	12.5%	85%	5%	5%	5%
		Funding	12.5%	100%	0%	0%	0%
		Ethics and permissions	12.5%	100%	0%	0%	0%
		Conducted study	12.5%	50%	50%	0%	0%
		Data entry and analysis	12.5%	95%	0%	5%	0%
		Drafted manuscript	12.5%	100%	0%	0%	0%
		Edited manuscript	12.5%	60%	5%	30%	5%
		Managed manuscript submission	12.5%	100%	0%	0%	0%
				86.3%	**7.5%**	**5.0%**	**1.3%**
Chapter 6: Relaxation Breathing		Data entry and analysis	25.0%	100%	0%	0%	0%
		Drafted manuscript	25.0%	85%	15%	0%	0%
		Edited manuscript	25.0%	40%	15%	40%	5%
		Managed manuscript submission	25.0%	100%	0%	0%	0%
				81.3%	**7.5%**	**10%**	**1.3%**

DEDICATION

I dedicate this thesis to all the people who have either taken part in the research or have guided the process. In particular Madeleine Nowak who took me from virtual illiteracy to a published author and for the support of my family Bob, Gus and Gemma Bartlett, thank you all.

Doctor of Public Health Course Structure

To be awarded a Doctor of Public Health (DrPH) a student has to successfully complete 72 units of activities. The table below shows the units I completed in fulfilment of requirements for the DrPH.

Unit code	**Unit**	**Description**	**Weight**
TM6015	Doctoral Presentations	7 (page xix and xx)	6
TM6018	Doctoral Project	Project report: 2005 Sun Safety Award Two publications (number 2 and 3, page xviii)	6
TM5517	GIS Writing & Computer Skills for Public Health	Masters unit	3
TM5519	Training Primary Health Care Workers	Masters unit	3
NS5604	Contemporary Issues in Ageing and Health	Masters unit	3
TM5527	Independent Project	PTQ^{TM} anal implants: One publication (number 4, page xviii)	3
Doctor of Public Health Thesis		Publications include: 9 published manuscripts (numbers 1, 5-10, 12 and 13: page xviii) 1 accepted manuscript (number 11, page xviii)	48
Total			72

Publications, awards and presentations throughout doctoral studies

Publications

1. **Bartlett L**, Nowak M, Ho YH . Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Techniques in Coloproctology*. 2007;11:251-7

2. **Bartlett L**, Harrison S, Taylor C. Recognition and Reward of Local Government Sun-Safety Initiatives in North Queensland: An environmental health promotion pilot. *Journal of Environmental Health Australia*. 2008;8:41-9

3. **Bartlett L**, Harrison S, Nowak M, Taylor C. North Queensland sun-safety award: lessons learned from a health promotion pilot in local government. *Journal of Rural and Tropical Public Health*. 2009;8:

4. **Bartlett L**, Ho YH. PTQ™ anal implants for the treatment of faecal incontinence. *The British Journal of Surgery*. 2009;96:1468-75

5. **Bartlett L**, Nowak M, Ho YH. Impact of fecal incontinence on quality of life. *World Journal of Gastroenterology*. 2009;15:3276-82

6. **Bartlett L**, Sloots K, Nowak M, Ho YH. Biofeedback therapy for symptoms of bowel dysfunction following surgery for colorectal cancer. *Techniques in Coloproctology*. 2011;15:319-326:

7. **Bartlett L,** Sloots K, Nowak M, Ho YH. Biofeedback therapy for faecal incontinence: a rural and regional perspective. *Rural and Remote Health*. 2011;11:1630

8. **Bartlett L**, Sloots K, Nowak M, Ho Y-H. Biofeedback for faeca l incontinence: a randomized control study comparing exercise regimen. *Diseases of the Colon and Rectum*. 2011;54:846-856.

9. **Bartlett L**, Sloots K, Nowak M, Ho Y-H. Impact of relaxation breathing on the internal anal sphincter in patients with fecal incontinence. *The Australian and New Zealand Continence Journal*. 2012;18:38-45

10. **Bartlett L**, Nowak M, Ho Y. Faecal incontinence in rural and regional northern Queensland community-dwelling adults. *Rural Remote Health*. 2013;13:2563

11. **Bartlett L**, Sloots K, Nowak M, Ho YH. Supplementary home biofeedback improves quality of lif e in younger patients with fecal in continence *Journal of Clinical Gastroenterology*, 2013 ***(In press)***

12. Sloots K, **Bartlett L**. Practical strategies for treati ng postsurgical bowel dysfunction. *Journal of Wound, Ostomy, and Continence Nursing*. 2009;36:522-7

13. Sloots K, **Bartlett L**, Ho YH. Treatment of postsurgery bowel dysfunction: biofeedback therapy. *Journal of Wound, Ostomy, and Continence Nursing*. 2009;36:651-8

14. Mushaya C, **Bartlett L**, Schulze B, Ho Y. Ligation of intersphincteric fistula tract compared with advancement flap for complex anorectal fistulas requiring initial seton drainage. *American Journal of Surgery*. 2012;204:283-289.

15. Cross T, **Bartlett L**, Mushaya C, Ashour M, Ho Y. Glyceryl trinitrate ointment did not reduce pain after stapled Haemorrhoidectomy: a randomized controlled trial. *International Surgery*. 2012;97:112-119.

16. Mushaya C, Caleo P, **Bartlett L**, Buettner P, Ho Y H. Harmonic scalpel compared with conventional excision haemorrhoidectomy: Meta-analysis of randomized controlled trials. ***Submitted to*** *Techniques in Coloproctology*. 2011

Awards

- Growing the Smart State PhD Funding Program of $15,000 awarded for Supplementary Home Biofeedback Therapy for Faecal Incontinence study (2005 – 2010)

- L Bartlett, M Nowak, YH Ho. To explore reasons for discordance in disclosure of faecal incontinence between 2 measurement instruments. (Abstract published in International Surgery) Pacific Regional International College of Surgeons Meeting (in collaboration with North Australian Surgeons) 21 – 23 March 2008 **(Best Free Paper** –awarded free registration to the International College of Surgeons Congress held in Vienna**)**

- Faecal incontinence in North Queensland: Prevalence and management: 19th National conference on incontinence Alice Springs Convention Centre, Alice Springs, NT; 27 - 30 October 2010

    - *Faecal incontinence in North Queensland: Biofeedback exercise regimens compared (**Best Poster** - $300 prize & trophy);*

- Finalist for the Queensland Health Healthcare Improvement Symposium and Awards 2011: Abstract & Presentation of "*Bottoms up!"* Brisbane Convention and Exhibition Centre, 31 August 2011

Presentations:

- **Bartlett LM**, Sloots K, Nowak M, Ho YH . Biofeedback: a significant reduction in post-surgery bowel dysfunction. Royal Australasian College of Surgeons 75th Annual Scientific Congress, 15/5/2006.

- **Bartlett LM**, Sloots K, Ho YH. Supplementary Home Biofeedback Therapy for Faecal Incontinence: A Pilot of 4 Patients. Tropical Health & Cancer Research in Clinical Practice, 19/7/2007.

- **Bartlett LM**, Sloots K, Ho YH. Biofeedback Therapy for Bowel Dysfunction following surgery for colorectal cancer. Tropical Health & Cancer Research in Clinical Practice, 19/7/2007.

- **Bartlett LM**, Cross N, Cross N, Huth N, Jackson S, Jensen A, Jongkryg M, King J, Lee P, Nugent C, Passmore J, Phillips R, Webster K , Wedel C, Baker M. Sun Protection Behaviour: Townsville and Thuringowa Community Markets. Tropical Health & Cancer Research in Clinical Practice, 20/7/2007.

- **Bartlett LM**, Harrison S. Recognition and reward of local government sun safety initiatives in North Queensland: The community sun safety award, a health promotion pilot model. Tropical Health & Cancer Research in Clinical Practice, 20/7/2007.

- **L Bartlett**, M Nowak, YH Ho. To explore reasons for discordance in disclosure of faecal incontinence (FI) between 2 measurement instruments. (Abstract published in International Surgery) Pacific Regional International College of Surgeons Meeting (in collaboration with North Australian Surgeons) 21 – 23 March 2008 **(Best Free Paper)**

- **Bartlett LM.** Prevalence of Faecal Incontinence in North Queensland: 25th Annual North Queensland Conference / 19th Annual ACTM Scientific Meeting 11th to14th June 2010

- **Bartlett LM**, Sloots K, Ho YH. Faecal incontinence in North Queensland: Prevalence and management: 19th National conference on incontinence Alice Springs Convention Centre, Alice Springs, NT; 27th to 30th October 2010. 3 Posters presented at this conference :

  - *Faecal incontinence in North Queensland: Biofeedback exercise regimens compared (**Best Poster** - $300 prize & trophy);*
  - *Faecal incontinence in North Queensland: Prevalence in regional and rural communities;*
  - *Faecal incontinence in North Queensland: Relaxation breathing, a component of a holistic biofeedback therapy*

- **Bartlett LM,** Sloots K. Finalist for the Queensland Health Healthcare Improvement Symposium and Awards 2011: Abstract & Presentation of "*Bottoms up!"*

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LIST OF APPENDICES

CHAPTER 1: INTRODUCTION

Context

The research conducted in this thesis was undertaken in Townsville, north Queensland, Australia. Clinical studies were conducted at the Townsville Hospital, a publicly funded regional hospital with a large rural catchment area in northern Queensland, while the faecal incontinence prevalence survey included the area from Bowen west to the Northern Territory border and north to the Torres Strait, a population of 568,000 (*Far North Queensland (FNQ): 271,000; North Queensland (NQ):297,000*; Fig 1.1).

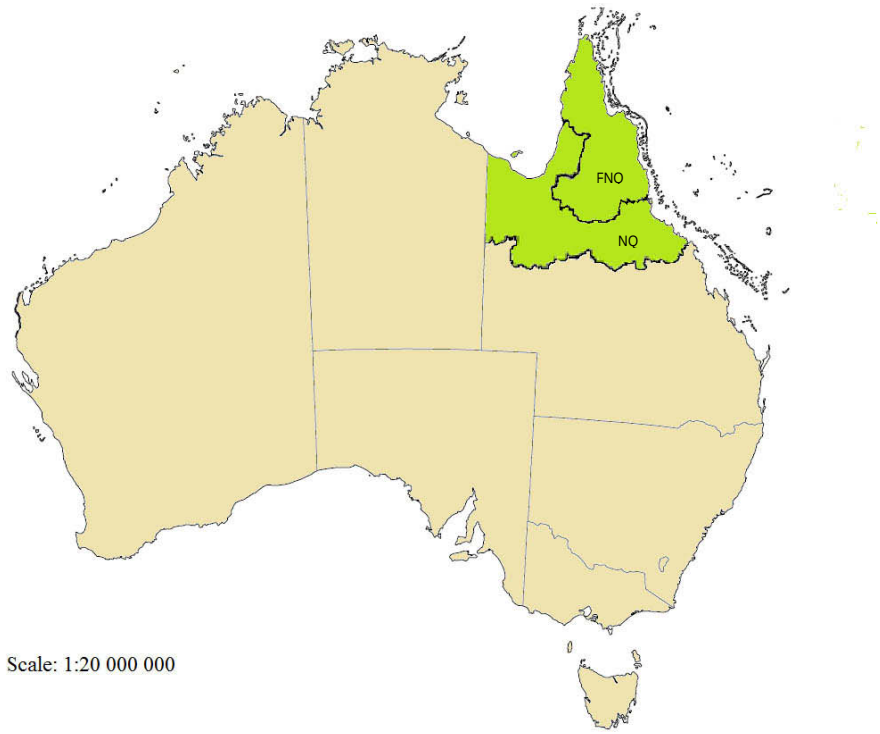

Figure 1.1: Rural and regional North and Far North Queensland population surveyed for faecal incontinence

Definition of faecal incontinence

There is no internationally accepted definition for faecal incontinence. In 1995 it was defined as "the involuntary or inappropriate passage of faeces" by the Royal College of Physicians. The World Health Organisation and International Continence Society developed the broader term of anal incontinence, which they defined as the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem [1].

Faecal incontinence, a symptom resulting from various causes, is the involuntary loss of liquid or solid stool with (urge related) or without (passive) the patient's awareness. It ranges from an occasional leakage of stool while passing gas to a complete loss of bowel control. Faecal incontinence may result in extreme embarrassment, loss of self-respect, psychiatric disorders, and withdrawal from the community with a resulting loss of economic productivity. This socially disabling condition has been largely neglected by Australian medical and public health research organisations with very little systematic research being conducted to determine the true burden of disease on individuals in regional and rural Australia.

Three community-based faecal incontinence studies have been conducted in Australia. They report prevalence of between 11.2% [2] and 15% [3] in residents over 18 years of age from Sydney, New South Wales and 2.9% in over 15 year old South Australians [4]. Faecal incontinence prevalence of 20.7% was reported at the Townsville Hospital outpatient gynaecology and colorectal clinics [5]. Studies conducted overseas also provide a wide variation in prevalence estimates ranging from 2% - 17%, largely due to using inconsistent definitions, poor bias minimization and not using validated, self-administered, anonymous questionnaire [6].

Study aims:

- *Identification of a workable definition of faecal incontinence for community dwelling adults in rural and regional Australia*
- *Measurement of the prevalence and burden of faecal incontinence in the northern Queensland population.*

Disclosure of faecal incontinence

Little has been written about the reasons people do not disclose faecal incontinence to their general practitioner or treating physician. This may be because faecal incontinence transgresses one of the basic norms we are taught from infancy [7]. Freud proposed that defecation control was an important part of ego development [8]. From about 4 years of age we are taught that passing stool in our underclothes is naughty and unacceptable [7]. There are complex arbitrary rules for acceptable elimination behaviour – those who cannot or will not comply are stigmatized and labelled as incontinent [9]. Most adults have difficulty describing the bowel control process [7] and there are no positive words or connotations regarding defecation in western societies. Avoiding excreta, a source of infection and disease,

was originally a survival tactic and faeces elicit disgust in adults from a range of cultures [10].

Barriers known to prevent people seeking treatment for urinary incontinence may also be applied to faecal incontinence [11]. These include:

- Stigma / Taboo
- Embarrassment / shame
- Doctors' gender
- Fear of institutionalization / preserving independence
- Health expectations of seniors
- Being perceived as a malingerer
- Rationing of physicians time / community nurse appointments
- Not troubling physician about every small thing
- Confidentiality issues
- Fear of others (including doctors) reactions (disgust) to disclosure
- Beliefs / attitudes about causes of incontinence
- Lack of knowledge about:
  - prevalence
  - where to get help
  - whether treatable

In 2003 researchers used two validated survey tools to investigate the prevalence of faecal incontinence in the Townsville Hospital colorectal and urogynaecology outpatient clinics [5]. There was a significant difference in disclosure of faecal incontinence between the two tools used that was not investigated at the time.

Study aims:

- To investigate the disclosure discordance
- To develop an improved faecal incontinence survey instrument by exploring discordance between existing validated survey instruments

Diagnosis

Severity of faecal incontinence can be determined by:

- History taking by health professionals to rule out other disorders (Diarrhoea; Perianal leakage of pus or mucus due to haemorrhoids, fistulas or neoplasms)
- Physical examination of the perianal area to assess sensation, inspect for fistulas, scars or gaping anus (possible sphincter dysfunction). Digital rectal examination can determine

sphincter-resting tone and squeeze pressure and normally identifies most cases of faecal impaction.

- Diagnostic tests to clarify anatomy and function, and choice of therapy include:
  - Anorectal manometry
  - Anal endosonography
  - Measurement of nerve conduction

Impact of faecal incontinence on quality of life

Faecal incontinence can be measured a number of ways; descriptively, by its severity (frequency of incontinence episodes and stool type), and by the impact it makes on a person's quality of life. A patient may limit the severity of their faecal incontinence by altering their lifestyle e.g. reducing activities and staying close to the toilet at home. Such a patient would have "severe" faecal incontinence by a quality of life measure but not by a severity measure.

While generic quality of life tools such as the Short Form (36) Health Survey [12] demonstrate functional impairment caused by faecal incontinence when compared with those who are continent, there is concern about the ability of these tools to detect small changes or compare impact on quality of life in different people with the same disease [13]. The Fecal Incontinence Quality of Life Scale [14], a validated and sensitive disease specific quality of life survey tool, has been recommended for use in Australian community dwelling adults [15].

Study aims:

- *To determine the impact of faecal incontinence on the quality of life of community dwelling adults in rural and regional areas*

Treatments

Faecal incontinence is a leading reason for nursing home admission. The prevalence of faecal incontinence of 20% in northern Queensland outpatient clinics [5] should direct public health focus toward prevention, early detection and conservative, cost effective treatments to minimize the effect it has on the health economy.

There are a number of treatments for faecal incontinence, with the most conservative including dietary and medication management, biofeedback therapy and rectal irrigation. More invasive options range from injectable anal implants to surgical options such as sacral

nerve stimulation, dynamic graciloplasty, artificial bowel sphincter and colostomy as a final resort.

Biofeedback is a first-line therapy in cases of mild to moderate faecal incontinence which have not responded to simple dietary advice or medication [16]. Biofeedback treatment for faecal incontinence was first reported in 1974 [17]; it converts pressure readings from an anal sensor to a display screen for visual feedback. Biofeedback has no known side effects and is considered a safe conservative treatment [18]. Recent studies have reported symptomatic improvement in 40-70% of patients [19, 20].

The Townsville Hospital has offered a biofeedback treatment program for faecal incontinence, constipation and pelvic pain since 2002. The program consists of behavioural strategies and biofeedback therapy in a series of weekly one-on-one sessions with a biofeedback therapist.

Study aims:

- *To assess the effect of different anal sphincter and pelvic floor exercises on outcome*
- *To determine any differences in outcome by location*
- *To assess the outcome in patients with post-surgery bowel dysfunction following colorectal cancer surgery*
- *To determine whether supplementary home biofeedback improves patient outcomes*

Episodes of faecal incontinence, especially in public, can cause anxiety. One further aspect of biofeedback treatment programs is relaxation breathing. No previous research has been undertaken to assess this component of biofeedback therapy for faecal incontinence.

Study aims:

- *To assess the effect of relaxation breathing on the internal anal sphincter in people with faecal incontinence*

Conclusion

Prevention and effective management of faecal incontinence can reduce the morbidity of this stigmatising condition. An improved understanding of the epidemiology of faecal

incontinence will assist in developing effective strategies to encourage prevention, disclosure and improve management of this disease.

If the burden of faecal incontinence is to be reduced, a more complete exploration is needed of:

- the condition in regional and rural community dwelling adults
- the effectiveness of locally available conservative treatments and how others can be developed to enable:
    - a broader reach of therapists
    - individual self-management

Reference list

1. Norton C, The Development of Bowel Control, in *Bowel Continence Nursing*, Norton C, Chelvanayagam S, Editors. 2004, Beaconsfield Publishers Ltd: Beaconsfield. p. 1-13.

2. Kalantar JS, Howell S, Talley NJ, Prevalence of faecal incontinence and associated risk factors; an underdiagnosed problem in the Australian community? *The Medical Journal of Australia*, 2002. 176(2): 54-7.

3. Lam TCF, Kennedy ML, Chen FC, Lubowski D, Talley NJ, Prevalence of faecal incontinence: obstetric and constipation risk factors: a population based study. *Colorectal disease*, 1999. 1: 197-203.

4. Avery JC, Gill TK, MacLennan AH, Chittleborough CR, Grant JF, Taylor AW, The impact of incontinence on health-related quality of life in a South Australian population sample. *Australian and New Zealand Journal of Public Health*, 2004. 28(2): 173-9.

5. Ho YH, Muller R, Veitch C, Rane A, Durrheim D, Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. *Australian Journal of Rural Health*, 2005. 13(1): 28-34.

6. Macmillan AK, Merrie AE, Marshall RJ, Parry BR, The prevalence of fecal incontinence in community-dwelling adults: a systematic review of the literature. *Diseases of the Colon & Rectum*, 2004. 47(8): 1341-9.

7. Norton C, Nurses, bowel continence, stigma, and taboos. *Journal of wound, ostomy, and continence nursing*, 2004. 31(2): 85-94.

8. Freud S, Character and anal eroticism. *Collected Papers London: Hogarth*, 1908:172.

9. Goffman E, Notes on the Management of Spoiled Identity. 1963, New Jersey: Prentice Hall.

10. Curtis V, Biran A, Dirt, disgust, and disease. Is hygiene in our genes? *Perspectives in Biology and Medicine*, 2001. 44(1): 17-31.

11. Horrocks S, Somerset M, Stoddart H, Peters TJ, What prevents older people from seeking treatment for urinary incontinence? A qualitative exploration of barriers to the use of community continence services. *Family Practice*, 2004. 21(6): 689-96.

12. Rothbarth J, Be melman WA, Meije rink WJ, Stiggelbout AM, Zwinder man AH, Buyze-Westerweel ME, Delemarre JB, What is the impact of fecal in continence on quality of life? *Diseases of the Colon & Rectum*, 2001. 44(1): 67-71.

13. Baxter NN, Rothenberger DA, Lowry AC, Measuring fecal incontinence. *Diseases of the Colon & Rectum*, 2003. 46(12): 1591-605.

14. Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, Wexner SD, Bliss D, Lowry AC, Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Diseases of the Colon & Rectum*, 2000. 43(1): 9-16.

15. Fallon A, Wes taway J, Moloney C, A systematic review of psychometric evidence and expert opinion regarding the assessment of faecal i ncontinence in older community-dwelling adults. *International Journal of Evidence-Based Healthcare*, 2008. 6(2): 225-259.

16. Norton C, K amm MA, Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults--a systematic review. *Alimentary pharmacology & therapeutics*, 2001. 15(8): 1147-54.

17. Miller NE, Editorial: Biofeedback: evaluation of a new technic. *The New England Journal of Medicine*, 1974. 290(12): 684-5.

18. Wald A, Biofeedback for fecal incontinence. *Gastroenterology*, 2003. 125(5): 1533-5.

19. Enck P, Schafer R, Biofeedback applications in gastroenterology. *European Journal of Gastroenterology & Hepatology*, 1996. 8(6): 534-9.

20. Heymen S, Jones KR, Ringel Y, Scarlett Y, Whitehead WE, Biofeedback treatment of fecal incontinence: a critical review. *Diseases of the Colon & Rectum*, 2001. 44(5): 728-36.

CHAPTER 2: DISCLOSURE

In a study conducted at the Townsville hospital urogynaecology and colorectal outpatient clinics, faecal incontinence data were collected using two survey tools: a Self-Administered Faecal Incontinence Questionnaire (Appendix 1a) [1] which included the 29 question Fecal Incontinence Quality of Life Scale [2], and the Cleveland Clinic Florida Fecal Incontinence Score questionnaire (Appendix 1b) [3]. There was a significant discordance between the disclosure of faecal incontinence obtained using these two instruments in the same group of patients [1, 3].

Study aims:

- *To explore the reasons for disclosure discordance*
- *To develop an improved faecal incontinence survey instrument by exploring discordance between existing validated survey instruments*

Publications arising from this chapter

2.1 Survey tool discordance

Bartlett L, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Techniques in Coloproctology*. 2007;11:251-7

My estimated contribution was 77% (Contributors table, page xv)

References

1. Ho YH, Muller R, Veitch C, Rane A, Durrheim D, Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. *Australian Journal of Rural Health*, 2005. 13(1): 28-34.

2. Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, Wexner SD, Bliss D, Lowry AC, Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Diseases of the Colon and Rectum* 2000. 43(1): 9-16.

3. Jorge JM, Wexner SD, Etiology and management of fecal incontinence. *Diseases of the Colon and Rectum*, 1993. 36(1): 77-97.

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ORIGINAL ARTICLE

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Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods

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Abstract Aims We explored reasons for discordance in disclosure of faecal incontinence (FI) between 2 measurement instruments: the Self Administered Faecal Incontinence Questionnaire (SAFIQ) and the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI). **Methods** Patients ≥18 years attending the urogynaecology (n=135) and colorectal (n=148) outpatient clinics at The Townsville Hospital, a referral centre serving regional North Queensland, Australia, were invited to complete the SAFIQ and answer questions from the CCF-FI asked by their treating doctor. Selected patients undertook semi-structured interviews. **Results** 262 patients completed both questionnaires. The prevalence of FI in this population was 25.6% (SAFIQ) and 29.9% (CCF-FI). 24% disclosed FI on both instruments, 3.1% on SAFIQ only and 6.1% on CCF-FI only. Major reasons for non-disclosure were: FI historical but not current; problem not considered as FI by patient; SAFIQ too long; condition embarrassing; doctor considered too busy; patient wanted to focus on primary reason for consultation; and doctor explained that a one-off bout of uncontrollable diarrhoea was not FI. Interviewees reported they would respond to FI questions initiated by their general practitioner (GP) during regular consultations, or in a generic questionnaire in the GP's surgery. **Conclusions** GPs could identify patients with FI by initiating discussions during routine consultations. Such patients could then be referred to colorectal surgeons for treatment. A more specific definition of FI, which excludes historical data and isolated instances of diarrhoea, is desirable. A measurement instrument suitable for population surveys should contain simple language and acknowledge issues of embarrassment.

Key words Disclosure • Faecal incontinence • General practice • Stigma

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Introduction

Faecal incontinence (FI) is defined as a loss of voluntary control of the passage of liquid or solid stool [1]. This condition has been referred to as "the silent affliction" [2] or "the unvoiced symptom" [3], because of the associated social stigma [1]. FI can have a profound negative impact on a person's quality of life, including social and economic status [4].

Three community FI studies have been conducted in Australia; two showed a high prevalence of FI. Of the two studies conducted in Sydney, New South Wales among adults 18 years and over, one reported an FI prevalence of 11.2% [5] and the other a prevalence of 15% [6]. The third

study conducted in metropolitan and rural South Australia with populations greater than 1000 people found a prevalence rate of 2.9% among those 15 years and older [7]. These Australian studies, like the FI studies conducted overseas [1], provide a wide variation in prevalence estimates due to differences in: FI definition; age and type of participant; measurement tools; and poor bias minimization [1]. In addition, a recent study conducted in outpatient clinics (urogynaecology and colorectal) in Townsville, North Queensland reported an FI prevalence of 20.7% [8] in this high-risk population.

Increasing age is one of the major risk factors for FI [5, 6, 8–14]. Australia, like other developed countries, has an aging population and the proportion of the population over the age of 65 years is expected to increase from 13% in 2002 to more than 27% by 2051 [15]. Currently it has been suggested that 16%–25% of those above the age of 60 years and approximately 50% of nursing home residents suffer with FI [2, 5–7, 16]. Indeed, FI is a major reason for placing elderly family members in a nursing home [17–19]. Lack of bowel control has major economic consequences [18], and whilst the debate about the health costs of an aging population continues, the health costs associated with untreated FI will rise. Early disclosure of FI is important since early intervention may not only lead to better treatment outcomes [20–22], but also to an improved quality of life [23], both of which may result in a reduced economic burden to the patient and the community [18].

In the study of FI prevalence in hospital outpatient clinics in Townsville [8], data were collected using two survey tools: a Self Administered Faecal Incontinence Questionnaire (SAFIQ) [8] and the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI) questionnaire [9]. Having reviewed the original data significant discordance was found in the prevalence rates obtained using these two instruments with the same group of patients [8]. The aim of this study was to explore the reasons for this discordance as a prelude to developing a reliable instrument to be used to determine the prevalence of FI in the North Queensland community.

Materials and methods

This study was designed to replicate the FI prevalence study conducted at The Townsville Hospital (TTH) in 2003 [8], with the aim of exploring reasons for the discordance of the results using the two measurement instruments. Participants were specifically drawn from the urogynaecology and colorectal outpatient clinics in order to obtain sufficient numbers of participants for the study. Whilst there is a higher incidence of undiagnosed FI in these clinics [8, 24], this was not the reason most patients sought medical treatment. Of the 318 patients who attended these clinics during this study period, only 7 were referred to the TTH biofeedback clinic for treatment of FI.

Participants

The study participants were all eligible patients visiting the urogynaecology and colorectal clinics of TTH between 5 August and 25 November 2004. Eligible patients were at least 18 years of age, not pregnant, with no terminal illness, mental illness, or gastrointestinal stoma. All participants signed informed consent forms.

Instruments

Two instruments were used to measure FI. The Self Administered Faecal Incontinence Questionnaire (SAFIQ) [8], which was developed to determine the prevalence, risk factors, severity and impact of FI in an Australian population, contains questions on patient demographics (3 questions); alcohol consumption (2 questions); pre-existing medical conditions (10 questions) and prior surgeries known to be risk factors for FI (5 questions). Patients who answered 'yes' to the question "Do you ever accidentally soil your clothes or underclothes with faeces" then proceeded to questions relating to the frequency (2 questions), severity (3 questions) and management (9 questions) of FI, and a further 29 questions seeking information on the impact of FI on their quality of life using the validated Faecal Incontinence Quality of Life Scale [10].

The comparison instrument used was the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI) [9]. This questionnaire was administered in a standardised manner by the attending medical practitioner who initially asked "Have you ever soiled your underwear with faeces?" The CCF-FI contains five questions on solid and liquid faecal soiling, flatus control, pad wearing and adjustments to daily living made necessary by FI. This frequently used instrument has been shown to provide both valid and reproducible results [9, 25].

For the purposes of this study FI was defined as patients having solid and/or liquid soiling as reveald by the CCF-FI.

Study procedure

The study procedure has been published previously [8]. Briefly, we performed a cross-sectional survey of patients attending the colorectal and urogynaecology clinics at the hospital. All patients attending these clinics during the study period were invited to participate in the study. After screening to ensure their eligibility for the study, subjects completed the TTH patient consent form.

Participants then completed and returned the SAFIQ, with assistance being available if requested. They were also given a sealed envelope containing the CCF-FI scoring form for the treating doctor to complete. The CCF-FI was also returned to the researcher by the patients after their consultation. The answers to the questions on the presence or absence of FI were compared on the two questionnaires for each participant. In addition, brief semi-structured interviews were conducted with patients who provided discordant responses to the FI disclosure questions on the two questionnaires. The interview related to: the language or terminology used; difficulty or ambiguity of the questions; and possible embarrassment with disclosure. Further questions

explored whether they decided to change their responses to the SAFIQ after speaking to the doctor and whether they would be happy for their general practitioner to ask these questions during routine checkups. Finally an attempt was made to determine the individual's reason for the discordance in their responses. For each discordant patient interviewed another patient, who reported no FI on both instruments, was randomly selected. These persons were interviewed to determine whether they would seek treatment if they developed FI in the future, and also for their feedback on the questionnaires.

Ethics

Ethics approval for the study was obtained from the ethics committees of The Townsville Hospital and James Cook University prior to the commencement of the study.

Statistical analysis

Mean and range were used to describe age. Prevalence was described using 95% confidence intervals (95% CI). Analysis of categorical variables was conducted using Fisher's exact test, while exact trend tests were used for items with underlying ordinal structure. The agreement of FI presence between the two instruments was described using Cohen's Kappa. A significance level of 0.05 was adopted a priori.

Results

Response rate

A total of 318 eligible patients attended the gynaecological clinic (n=151, all women) and the colorectal clinic (n=167; 69 men, 98 women) during the study period, and 89.0% (n=283) of the eligible patients agreed to participate in the study and completed the SAFIQ (Table 1). Of these patients, 83.2% (n=264) returned a CCF-FI continence scale completed by their attending physician, giving a final study response rate of 83.3%. The mean age (range) of participants was 56.8 (19–88) years for men and 53.5 (18–86) years for women, which was representative of patients attending the clinics (Table 1).

Prevalence of FI and concordance between questionnaires

The prevalence of FI in the study population estimated with the SAFIQ was 25.6% (95% CI, 20.5%–30.7%) with no significant difference between men (25.0%; 95% CI, 14.0%–36.0%) and women (25.8%; 95% CI, 20.1%–31.5%) (p=1.000). The prevalence was not significantly higher among those attending the colorectal clinic (28.4%; 95% CI, 21.1%–35.7%) than among participants from the urogynaecology clinic (22.6%; 95% CI, 15.5%–29.7%) (p=0.277). The prevalence of FI determined with the CCF-FI (solid and/or liquid soiling score ≥1) was consistently higher than that found using the SAFIQ, with the overall prevalence being 29.9% (Table 2).

There was a 90.8% agreement (kappa=0.78; 95% CI, 0.69–0.86) between the prevalence rates measured using the SAFIQ and the CCF-FI (Table 3). Presence of FI was reported on both survey instruments by 63 patients (14 male, 49 female), and absence of FI was reported on both instruments by 175 patients. There were 16 participants (4 male, 12 female) who reported FI only on the CCF-FI scale and 8 patients (1 male, 7 female) who reported FI only on the SAFIQ.

More than half the participants who gave discordant responses were interviewed (15 of 24). An additional five participants explained their discordant answers in written form on the questionnaires. The remaining four participants who gave discordant responses left the clinics before they could be interviewed. Of the 20 participants who were interviewed, eight had FI, with five reporting the condition only on the CCF-FI and three reporting FI only on the SAFIQ. Of the 12 without FI, four reported having the condition on the SAFIQ and eight reported it only on the CCF-FI. Of the four participants who provided discordant answers but left before they could be interviewed, one disclosed FI on the SAFIQ and three reported FI to the doctor administering the CCF-FI. Discordant answers

Table 1 Age and gender of participants from the urogynaecological and colorectal clinics at The Townsville Hospital

Clinic	Gender	Attended & eligible		Participated	
		n	Age[a]	n (%)	Age[a]
Colorectal	Male	69	55.9 (19–88)	60 (87.0)	56.8 (19–88)
	Female	98	54.1 (19–86)	88 (89.8)	53.7 (20–86)
Urogynaecological	Female	151	53.1 (18–91)	135 (89.4)	52.6 (18–82)
Total		318	54.0 (18–91)	283 (89.0)	53.8 (18–88)

[a] Mean (range)

Table 2 Prevalence of faecal incontinence among participants from the urogynaecological and colorectal clinics at The Townsville Hospital, by gender, clinic and survey instrument. There was no significant difference in FI prevalence between those attending the two clinics (p=0.227)

Clinic	Gender	SAFIQ		CCF-FI	
		Prevalence, %	Patience, n[a]	Prevalence, %	Patients, n[a]
Colorectal	Male	25.0	15/60	30.5	18/59
	Female	30.7	27/88	37.3	31/83
Urogynaecological	Female	22.6	30/133	24.6	30/122
Total		25.6	72/281	29.9	79/264

SAFIQ, Self Administered Faecal Incontinence Questionnaire [8]; *CCF-FI*, Cleveland Clinic Florida Fecal Incontinence Score [9]
[a] Values are number of patients reporting FI/number of patients responding to the question

Table 3 Concordance of results between CCF-FI and SAFIQ questions measuring faecal incontinence among patients from the urogynaecological and colorectal clinics at The Townsville Hospital

SAFIQ	CCF-FI[a]			Measure of agreement (Kappa)	p value
	No	Yes	Total		
Current stydy					
No	175	16	191	0.776	<0.0001
Yes	8	63	71		
Total	183	79	262		
Ho et al. [8]					
No	259	31	290	0.560	<0.0001
Yes	26	55	81		
Total	285	86	371		

[a] *CCF-FI* solid and/or liquid soiling score >0

among those without FI (n=12) were predominantly due to a perceived difference in the two questions or poor understanding of FI (Table 4). Doctors administering the CCF-FI instrument asked "Have you ever soiled…" whereas the question on the SAFIQ was "Do you ever accidentally soil…". Four participants who reported having FI on the CCF-FI but not on the SAFIQ had suffered from FI in the past, but did not have these symptoms at the time of the study. Two participants reported FI on the SAFIQ, but not on the CCF-FI after the attending medical practitioner explained that uncontrollable diarrhoea as a reaction to food, medication or infection was not FI. However, four participants did not report FI on the SAFIQ but were recorded as having FI by the doctor. At interview, each explained that they had had a one-off bout of uncontrollable diarrhoea as a reaction to either food or laxatives. Another two participants had misinterpreted the word "soiling" to refer to urinary incontinence or menstrual loss. Failure of consistent disclosure in patients with FI (n=8) was associated with a variety of issues (Table 4). Four patients did not realise that slight staining was considered to be FI, with one of them describing the occurrence only when lifting heavy weights. Embarrassment associated with the location for completing the SAFIQ (hospital waiting room, n=2), discussing the issue with a male doctor (n=1), concern that the doctor was too busy (n=2), or wishing to focus on the current medical problem (n=1), were all given as reasons for nondisclosure. In addition, one participant had "forgotten" she had FI and another reported that the soiling was discharge from an abscess.

After adjusting for all available information from study participants, the prevalence of FI in this population was 26.0% (95% CI, 20.9%–31.1%).

Further information obtained from participants without FI

A sample of participants without FI (n=13) was interviewed to obtain more insight into issues of disclosure relating to FI. All patients indicated they would seek help if they developed FI in the future, with most (12 of 13) identifying their general practitioner (GP) and one indicating a hospital doctor as the preferred initial point of con-

Table 4 Themes identified during interviews with participants who provided discordant answers about faecal incontinence

Failed to disclose on	Patient	Has FI now	Gender	Non-disclosure themes											
				Had FI in past - not now	Single bout of uncontrolled diarrhoea	Does not consider problem FI	Embarassed	Doctor too busy	Urinary incontinence or menstrual bleeding	SAFIQ too long	Denied having FI	Focus on other issues	Did not want to complete SAFIQ	Forgot I had FI	No FI if able to get to toilet
SAFIQ	1	y	F			✔									
	2	y	M				✔			✔					
	3	y	F			✔									
	4	y	F							✔				✔	
	5	y	F			✔	✔				✔		✔		✔
	6	n	F						✔						
	7	n	F	✔		✔									
	8	n	M		✔										
	9	n	M		✔	✔									
	10	n	F	✔	✔										
	11	n	F		✔										
	12	n	M	✔											
	13	n	F	✔											
CCF-FI	14	y	M								✔				
	15	y	F					✔							
	16	y	F	✔		✔		✔				✔			
	17	n	F		✔										
	18	n	F						✔						
	19	n	F	✔											
	20	n	F		✔										

tact. All participants indicated they would complete the SAFIQ in their GP's surgery or in a hospital clinic and that they would answer FI questions asked by their GP during a routine check-up. Most patients (9 of 13) said they would complete and return a postal FI survey using the SAFIQ. Another two participants suggested that statistics and information on prevention would provide an incentive for them to participate in the survey. In contrast, only one person said they may be prepared to answer the FI questions in a telephone survey, while the remainder (12 of 13) would not answer, citing inability to confirm interviewer credentials and embarrassment as reasons. Of these patients, 11 said they would be happy to participate in face to face interviews.

Discussion

The major findings of this study were that the prevalence of FI in the study population was high and that there was a substantial difference in the results using the two measurement instruments, with the discordance being predominantly due to issues of definition, understanding, terminology and embarrassment. Once adjusted for the measurement differences, the prevalence of FI was 26.0% (95% CI, 20.9%–31.1%). The prevalence of FI found in this study confirmed the high prevalence from an earlier survey in a similar population [8], with the proportion of participants reporting FI on both survey tools being 24% compared with 14.8% in the earlier study. This may be due to differences in the aims and related recruitment technique between the two studies. In the earlier study, patients were asked to participate in a survey to determine the prevalence of FI, while in the current study patients were asked to complete the questionnaires to help refine them for future use. This latter approach may have resulted in less embarrassment and hence higher levels of disclosure. The results from the SAFIQ were consistently lower than those obtained using the CCF-FI scale. The discordant responses among those without FI were predominantly due to misinterpretation of the questions. It was particularly evident that an explanation of the difference between consistent FI and an isolated episode of uncontrolled diarrhoea associated with short-term illness was required. This information was usually provided by the attending medical practitioner when completing the CCF-FI questionnaire and should be added to an upgraded version of the SAFIQ. In addition to a consensus definition of faecal incontinence that includes flatus, liquid or solid stool that impacts on quality of life [1], there may be a need for a more specific definition which includes a time frame and excludes isolated episodes associated with short-term illness. The discordant responses among participants with FI were predominantly due to issues relating to disclosure, particularly embarrassment. This is similar to disclosure issues in a study conducted in England [26] which found that: patients do not know the right terminology to discuss their bowel symptoms; attitudes to faeces are complex and embedded in social rules and conventions; and the approach of health care professionals can determine whether people seek help for this condition. It was suggested that using common public vocabulary would increase the likelihood of disclosure [26]. Direct questioning by primary care professionals has been shown to increase disclosure for other conditions such as urinary incontinence, which also have associated perceived social stigma [27]. Participants in this study who were asked about enabling greater disclosure of FI reported that they would feel comfortable if their GP initiated such questions during a routine medical examination.

Limitations of this study included the populations from which the participants were drawn, the small number of discordant participants, the fact that the participants were surveyed in the clinic waiting room (which may have reduced their willingness to disclose) and the fact that a validated questionnaire (CCF-FI) was compared with an only partially validated questionnaire (SAFIQ). Moreover, the mean age of patients at the urogynaecology clinic is low and may not well represent the general population, because the Townsville region population is younger than for Queensland and Australia, with 62.0% being aged less than 40 years compared with 56.8% for Queensland and 56.6% for Australia [28].

In conclusion, surveys to measure the prevalence of FI should ensure that ongoing FI is being measured and that the terminology used is not ambiguous. Using an anonymous survey tool should remove some of the problems associated with embarrassment. For surveys, embedding the FI questions within a questionnaire about bowel health may further reduce the level of embarrassment and encourage participation and disclosure. Higher disclosure rates may also be achieved using a postal survey given the strong response against telephone interviews of patients without FI in this study (12 of 13). Following the problems identified by participants completing the SAFIQ the survey instrument has been amended for an upcoming postal prevalence study. The inclusion of standard FI questions in GP patient management software for routine checkups would help to identify and therefore treat people with this complaint as early as possible. The results of this study suggest that people with colorectal or urogynaecological diseases may particularly benefit from the inclusion of these questions in routine medical examinations.

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References

1. Macmillan AK, Merrie AE, Marshall RJ, Parry BR (2004) The prevalence of fecal incontinence in community dwelling adults: a systematic review of the literature. Dis Colon Rectum 47:1341–1349
2. Johanson JF, Lafferty J (1996) Epidemiology of fecal incontinence: the silent affliction. Am J Gastroenterol 91:33–36
3. Leigh RJ, Turnberg LA (1982) Faecal incontinence: the unvoiced symptom. Lancet 1:1349–1351
4. Baxter NN, Rothenberger DA, Lowry AC (2003) Measuring fecal incontinence. Dis Colon Rectum 46:1591–1605
5. Kalantar JS, Howell S, Talley NJ (2002) Prevalence of faecal incontinence and associated risk factors; an underdiagnosed problem in the Australian community? Med J Aust 176:54–57
6. Lam TCF, Kennedy ML, Chen FC, Lubowski D, Talley NJ (1999) Prevalence of faecal incontinence: obstetric and constipation risk factors: a population based study. Colorectal Dis 1:197–203
7. Avery JC, Gill TK, MacLennan AH, Chittleborough CR, Grant JF, Taylor AW (2004) The impact of incontinence on health-related quality of life in a South Australian population sample. Aust N Z J Public Health 28:173–179
8. Ho YH, Muller R, Veitch C, Rane A, Durrheim D (2005) Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. Aust J Rural Health 13:28–34
9. Jorge JM, Wexner SD (1993) Etiology and management of fecal incontinence. Dis Colon Rectum 36:77–97
10. Rockwood TH, Church JM, Fleshman JW et al (2000) Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. Dis Colon Rectum 43:9–16; discussion 16–17
11. Nelson R, Norton N, Cautley E, Furner S (1995) Community-based prevalence of anal incontinence. JAMA 274:559–561
12. Thomas TM, Egan M, Walgrove A, Meade TW (1984) The prevalence of faecal and double incontinence. Community Med 6:216–220
13. Talley NJ, O'Keefe EA, Zinsmeister AR, Melton LJ 3rd (1992) Prevalence of gastrointestinal symptoms in the elderly: a population-based study. Gastroenterology 102:895–901
14. Drossman DA, Li Z, Andruzzi E et al (1993) U.S. householder survey of functional gastrointestinal disorders. Prevalence, sociodemography, and health impact. Dig Dis Sci 38:1569–1580
15. Australian Bureau of Statistics (2003) Population projections, Australia 2002 to 2101. ABS Catalogue No. 3222.0
16. Wald A (2005) Faecal incontinence in the elderly: epidemiology and management. Drugs Aging 22:131–139
17. Nelson RL (2004) Epidemiology of fecal incontinence. Gastroenterology 126:S3–S7
18. Miner PB Jr (2004) Economic and personal impact of fecal and urinary incontinence. Gastroenterology 126:S8–S13
19. Lahr CJ (1998) Evaluation and treatment of incontinence. Pract Gastroenterol 12:27–35
20. Rasmussen OO (2003) Fecal incontinence. Studies on physiology, pathophysiology and surgical treatment. Dan Med Bull 50:262–282
21. Brooks V (2002) Treat incontinence early. Nurs Stand 16:22
22. Hunter S, Anderson J, Hanson D, Thompson P, Langemo D, Klug MG (2003) Clinical trial of a prevention and treatment protocol for skin breakdown in two nursing homes. J Wound Ostomy Continence Nurs 30:250–258
23. Norton NJ (2004) The perspective of the patient. Gastroenterology 126:S175–S179
24. Manning J, Eyers AA, Korda A, Benness C, Solomon MJ (2001) Is there an association between fecal incontinence and lower urinary dysfunction? Dis Colon Rectum 44:790–798
25. Wang A, Guess M, Connell K, Powers K, Lazarou G, Mikhail M (2006) Fecal incontinence: a review of prevalence and obstetric risk factors. Int Urogynecol J Pelvic Floor Dysfunct 17:253–260
26. Norton C (2004) Nurses, bowel continence, stigma, and taboos. J Wound Ostomy Continence Nurs 31:85–94
27. Horrocks S, Somerset M, Stoddart H, Peters TJ (2004) What prevents older people from seeking treatment for urinary incontinence? A qualitative exploration of barriers to the use of community continence services. Fam Pract 21:689–696
28. http://www.townsville.qld.gov.au/about/atlas/age_1.asp accessed 26 June 2007

CHAPTER 2.2: Addendum

Table 2 in chapter 2.1 Survey tool disclosure: (Bartlett L, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Techniques in Coloproctology*. 2007;11:251-7) SAFIQ heading should read :

"Prevalence, % Patients, *n*[a]" not "Prevalence, % Patience, *n*[a]"

and

Table 3 in chapter 2.1 Survey tool disclosure: (Bartlett L, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Techniques in Coloproctology*. 2007;11:251-7) under SAFIQ heading should read :

"Current study" not "Current stydy"

CHAPTER 3: PREVALENCE

Systematic reviews have reported wide variations in estimates of the prevalence of faecal incontinence among community-dwelling adults (0% to 15.2%) with higher rates found in studies that effectively minimised bias [1, 2]. Two anonymous self-administered postal surveys conducted in Sydney, New South Wales, Australia reported the highest faecal incontinence prevalence in community-dwelling adults [3, 4]. Further cross-sectional studies of faecal incontinence using validated, self-administered, anonymous questionnaires have been recommended [1].

Studies conducted in 2004 [5] and 2005 [Chapter 2.1] reported faecal incontinence in over 20% of the Townsville hospital colorectal and urogynaecological clinic patients prompting concern about the level of faecal incontinence in the northern Queensland community. The magnitude of faecal incontinence in community-dwelling Queensland adults had not been assessed previously and may have significant consequences for the planning and development of treatment and support services in this state.

At June 2012, the estimated resident population of Queensland was 4.56 million people of whom 48% (2.19 million) reside in the greater Brisbane area, with approximately 70% (3.2 million) living within 150km of Brisbane central business district. The Townsville region in northern Queensland (1360km north west of Brisbane) has 4% of the population (184,697) and Cairns region in far northern Queensland (1705km north west of Brisbane) has 3.6% (165,859) of the Queensland population [6].

Study aim:

- *To determine the prevalence of faecal incontinence in rural and regional community-dwelling populations in North and Far North Queensland*

Publication arising from this chapter

3.1 Prevalence of faecal incontinence in community residing adults in northern Queensland

Bartlett L, Nowak M, Ho YH. Faecal incontinence in rural and regional northern Queensland community-dwelling adults. *Rural and Remote Health*. 2013;13:2563.

My estimated contribution was 89% (Contributors table, page xv)

References

1. Macmillan AK, Merrie AE, Marshall RJ, Parry BR, The pr evalence of fecal incontinence in co mmunity-dwelling adults: a systematic review of the literature. *Diseases of the Colon and Rectum* 2004. 47(8): 1341-9.

2. Pretlove SJ, Radley S, Toozs-Hobson PM, Thompson PJ, Coomarasamy A, Khan KS, Prevalence of anal incontinence according to age and gender: a systematic review and meta-regression analysis. *International Urogynecology Journal and Pelvic Floor Dysfunction*, 2006. 17(4): 407-17.

3. Lam TCF, Kennedy ML, Chen FC, Lubow ski D, Tal ley NJ, Prevalence of faecal incontinence: obstetric and constip ation risk fact ors: a p opulation based study. *Colorectal Disease*, 1999. 1: 197-203.

4. Kalantar JS, How ell S, Ta lley NJ, Prevalence of faecal incontinence and associated risk factors; an und erdiagnosed problem in the Australian community? *The Medical Journal of Australia*, 2002. 176(2): 54-7.

5. Ho YH, Mu ller R, Veitch C, Rane A, Durrhei m D, Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a h ospital-based outpatient study. *Australian Journal of Rural Health*, 2005. 13(1): 28-34.

6. Australian Bureau of Statistics, Regional Population Growth, Australia, 2011-12 *ABS Catalogue no. 3218.0*, 2013.

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ORIGINAL RESEARCH

Faecal incontinence in rural and regional northern Queensland community-dwelling adults

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ABSTRACT

Introduction: In Australia, faecal incontinence, the involuntary loss of liquid or solid stool with or without a person's awareness, has been reported in 8% of the South Australian and 11% of the urban New South Wales community-dwelling populations. Studies conducted in 2004 and 2005 reported faecal incontinence in more than 20% of colorectal and urogynaecological clinic patients at Townsville Hospital (a referral centre serving rural North Queensland). This prompted concern regarding the level of faecal incontinence in the community. The aim of this study was to investigate the prevalence of faecal incontinence in the North and Far North Queensland urban and rural communities.

Methods: The sample size was based on the New South Wales postal surveys (11% prevalence). Higher rates were expected in North/Far North Queensland, so prevalence there was estimated at 12.1% (confidence interval ± 2%, ie the true level to be between 10.1% and 14.1%). The sample for each of the Townsville, Cairns (in Far North Queensland) and rural/remote settings was calculated at 1022. The database for the present study was compiled using a systematic randomised process selecting two private names from each column on each page of the Cairns and Townsville White Pages® (Cairns: 1112 urban, 481 rural, 226 remote; Townsville: 1049 urban, 432 rural, 320 remote). The questionnaire covered personal demographics, health/risk factors, bowel habits, nutrition (fibre and fluid intake) and physical activity. Faecal incontinence was defined as accidental leakage of solid or liquid stool in the past 12 months that was not caused by a virus, medication or contaminated food. To improve the response rate a participation incentive of a chance to win a $250 voucher or one of ten $50 vouchers was offered in the initial mail-out. The initial survey was mailed out in July 2007; two follow-up surveys were mailed out to non-responders in September 2007 and January 2008. One hundred randomly selected non-responders were telephoned in February 2008.

Results: A total of 1523 responses provided a 48.1% response rate. Faecal incontinence prevalence was 12.7% (174/1366) with no gender or locality differences. Prevalence increased significantly with age in men (p=0.034), but not in women. Only 10 respondents with faecal incontinence consulted their doctor in the previous year for this reason. Incontinent respondents had

significantly more medical conditions including urinary incontinence, coeliac disease, irritable bowel syndrome, injury to the anus, bowel cancer, spinal cord disease, neurological disease and psychiatric problems (all, $p<0.05$). Stool-related accidental bowel leakage including faecal incontinence (defined), soiling with flatus or urgency, was 18.2%. An additional 3% were possibly incontinent, having disclosed leakage of mucus, bothersome or passive staining. Of the remaining respondents, 16.2% reported incontinent episodes due to an acute illness, 22.9% could not always differentiate between flatus and stool, and only 35.2% reported neither concerns with nor accidental bowel leakage.

Conclusions: There is a high level of untreated faecal incontinence in North/Far North Queensland communities. Demand for treatment will increase because of the ageing population and the expectations of younger, more assertive cohorts.

Key words: faecal incontinence, adult, community, demographic and age distribution, diet, disclosure, postal survey, prevalence, regional, severity, systemised random allocation.

Introduction

Accidental bowel leakage is rarely disclosed[1]. It can range from occasional loss of flatus, through staining of underwear with mucus or stool, to faecal incontinence, which the International Continence Society defines as the involuntary loss of liquid or solid stool that is a social or hygienic problem[2]. The impact of faecal incontinence on quality of life can be debilitating and embarrassing. Stringent coping strategies often alienate the sufferer from friends and family[3]. There is little awareness of it in the general community. Even sufferers confuse it with diarrhoea, faecal urgency, irritable bowel syndrome or inflammatory bowel disease[4].

Risk factors resulting in the development of faecal incontinence include congenital anorectal abnormalities; neurological or spinal damage; obstetric or anal trauma; anal or rectal cancers; inflammatory bowel disease; reconstructive bowel surgery; psychological problems; abdominal/pelvic irradiation; infections; reactions to medications, drugs or diet; rectal prolapse, anal fistula or haemorrhoids; immobility; increasing age; chronic constipation; obesity and poor management of diarrhoea or loose stool; and idiopathic causes[5-7].

Internationally, the prevalence of faecal incontinence in community-dwelling adults ranges from 0% to 15.2%[8]. Australian studies have estimated prevalence between 8%[9] and 11%[10,11] in community-dwelling adults, with telephone interviews being used in a South Australian study[9] and two postal surveys being conducted in Sydney, New South Wales[10,11]. Studies undertaken at the Townsville Hospital urogynaecology and colorectal outpatient clinics reported up to 26% of patients having the condition, with a considerable effect on their quality of life[3,12,13].

Currently up to 72% of nursing home residents suffer with faecal incontinence[14]. The proportion of Australians over the age of 65 is expected to increase from 13.4% of the population in 2007 to 25.3% of the population by 2047 and the percentage of those over the age of 85 will likely rise from 1.7% to 5.6%[15]. Many Australians wish to age in their homes rather than move into specialised care[16]. Increased demand for community-based incontinence services will be due to not only the ageing population[15] but also the fact that younger cohorts (baby boomers, X and Y generations) are more assertive and expect to have their needs satisfied[17]. World War II (age 85–90 in 2012) and post-war cohorts (67–84) are known as the silent generation and are stoic and reserved, respect clinicians and are more likely to comply with their recommendations. This general attitude may be reflected in their reticence to disclose embarrassing issues such as faecal incontinence and reluctance to seek treatment for this condition.

Baby boomers (47–66) are sceptical, questioning and expect pharmacological solutions to their age-related problems[17].

They are more likely to try novel treatments such as anal implants[18], sacral nerve or percutaneous tibial nerve stimulation[19] for their faecal incontinence, with the hope of finding a 'magic pill' or panacea[17]. With compulsory superannuation they are prepared to pay for healthcare services into their old age[15]. Generation X (36–46) treasure independence, are focused on their quality of life and work to fund their more balanced lifestyle. Their choice of health service providers are likely to be an economic decision and they will require more personalised support, shared decision-making and greater self-management[20]. The Y generation (18–36) are tolerant team players who value mentorship and have grown up with the internet and frequent technological change. They value excitement and instant gratification through email, messaging and social media and may adopt healthcare services via social media[17]; they may prefer self-management of faecal incontinence using telephone and tablet applications. For this and other age-related health problems the Ottawa Charter action areas of building healthy public policy, creating supportive environments, strengthening community action, developing personal skills and reorienting health services provide a useful framework to develop prevention, early intervention and treatment protocols[21].

This study was undertaken to investigate personal demographics, health/risk factors, bowel habits, nutrition intake (fibre and fluid) and physical activity in relation to faecal incontinence. Here the authors report the prevalence of faecal incontinence in community-dwelling adults and assess disclosure of accidental bowel leakage in regional and rural areas of North/Far North Queensland, Australia.

Methods

A sample of 3620 subjects was compiled from the 2006–2007 Cairns and Townsville White Pages® telephone directories (Cairns: 1112 urban, 481 rural, 226 remote; Townsville: 1049 urban, 432 rural, 320 remote) using systematic random sampling. The first non-business name and address was selected from each column between 90–100 mm and 190–200 mm from the top of the page. The sample addresses were updated from the 2007–2008 printed and online White Pages® directory prior to distribution. Where a subject no longer appeared in the directory the next alphabetically listed private address was chosen as a replacement.

The self-administered questionnaire (Appendix 1), a study information sheet, an incentive leaflet (return of the completed survey provided an opportunity to win a $250 or $50 voucher), an opaque incentive response envelope, and a reply-paid envelope were mailed to everyone on the database. The survey contained 62 questions in five sections including personal demographics (11) with additional questions about female obstetric history (8), health/risk factors (6), bowel habits (32), nutrition (fibre and fluid intake) (2) and physical activity (3).

Demographic questions included those related to age, gender, cohabitation, residence type, postcode, education level, country of birth, height, weight and indigenous status. Female obstetric history questions included menopausal status, number of natural and caesarean births, use of forceps/vacuum, episiotomy, post-tear stitches, hysterectomy and hormone replacement therapy. Health or risk factor questions included participant-perceived general health as well as factors, previously identified, as potentially causal for this condition[5-7] (Appendix 1).

Participants were asked for information about year and results of a colonoscopy. Questions about bowel habits included those related to frequency of defecation; stool type[22]; urgency; difficulty in emptying bowels; constipation and straining; accidental anal leakage and its effect on quality of life; and coping strategies used. Nutrition questions related to fluid and fibre intake. Activity questions related to normal daily activity, exercise and pelvic floor exercises.

The initial survey was mailed out in July 2007, followed by two follow-up surveys mailed to non-responders in September 2007 and January 2008. One hundred random non-responders were invited to answer the survey by phone in February 2008. All mail-outs contained reply-paid envelopes and covering letters explaining the purpose of the study. The follow-up mail-outs included a non-response/remove me from the database tool

seeking reasons for non-response. Anonymity of replies was maintained. Core faecal incontinence questions were adapted from the Cleveland Clinic Florida Fecal Incontinence Score (Wexner) which correlates well with clinical presentation of faecal incontinence and has been referred to as 'a tool of choice' for assessing faecal incontinence in community-dwelling older adults[23].

In this study, faecal incontinence was defined as accidental leakage of solid or liquid stool in the previous 12 months that was not caused by a virus, medication or contaminated food.

Statistics

Community prevalence and 95% confidence intervals (CI) of faecal incontinence and accidental bowel leakage were determined. Numerical data are given as mean value and standard deviation or median value and interquartile range (IQR), depending on the distribution. Comparisons between characteristics were conducted using χ^2 tests and χ^2 tests for trend, nonparametric Wilcoxon tests, and student's *t*-tests. Statistical analyses were conducted using Statistical Package for the Social Sciences Windows v17 (SPSS Inc., http:// www.spss.com). Throughout the analysis $p<0.05$ was considered statistically significant. The sample size calculation was based on the Sydney, New South Wales community postal surveys (faecal incontinence prevalence = 11%)[10,11]. The authors expected the North/Far North Queensland prevalence to be greater. Choosing 12.1% (10% higher) with a confidence level of ± 2% (ie true level to be between 10.1% and 14.1%), the sample size calculation for each of the Townsville, Cairns and rural settings was 1022. Systematic random sampling generated 3620 private names for the database.

Ethics approval

James Cook University Human Research Ethics Committee granted ethical approval (H2630).

Results

Of the 3620 surveys mailed out, 432 were returned to sender as 'no longer at this address' (18 of these were reported deceased); nine completed surveys were invalid (one under-age, two nursing home residents, six living outside North/Far North Queensland). Fourteen of the 100 random numbers telephoned were inactive phone numbers. Of the remaining 3165 potential participants, 95 gave reasons for not wishing to participate; 1523 questionnaires were returned giving a response rate of 48.1%.

Valid responses were from 628 (41.0%) men and 891 (58.5%) women. Male respondents were older than female respondents (mean age: 57.3 (95% CI: 56.2–58.5) vs 52.3 (51.3–53.4) years, $p<0.001$) and had a marginally higher mean body mass index (27.6 (27.3–28.0) vs 26.7 (26.3–27.1), $p=0.001$). Although more women (11.3%) than men (7.8%) resided alone ($p<0.001$), there were no significant differences between the genders with regard to type or location of residence, level of education, occupation type, country of birth or indigenous status.

The prevalence (95% CI) of faecal incontinence was 12.7% (10.9–14.5%, Table 1). Overall, there was no significant difference between genders (men 12.6%, women 12.8%) or residence (regional centre or rurally). Prevalence increased significantly with age in men (18–39: 3/65, 4.6% (0.0–9.9%); 40–59: 31/251, 12.4% (8.3–16.4%]; >60: 38/252, 15.1% (10.6–19.5%], $p=0.034$) but not in women, although it was similar for both genders over 40 years of age (Fig1).

Of those with faecal incontinence, 54 (34.8%) reported urge incontinence, 19 (12.3%) passive incontinence and 44 (28.4%) both passive and urge incontinence. Only 28.1% of incontinent participants could always differentiate between flatus and stool compared with 53.5% of continent respondents ($p<0.001$, Table 2). Nocturnal bowel leakage was a problem for 41 (26.3%) of incontinent respondents. While 59 (36.6%) incontinent respondents had problems modifying their diet to control their bowel, 49 (32.7%) did not know which medications would control their bowels and 56 (34.1%) felt they had no control over their bowels; only 11 (7.1%) had sought treatment for this condition. More than 38% (64) of respondents with faecal incontinence reported having first degree relatives with 'bowel problems'.

Most incontinent participants (130/174, 74.7%) reported incontinent episodes occurring less than once per month, 32 (18.4%) more than once a month, 10 (5.7%) more than once a week, and 2 (1.1%) at least once per day (Table 3, Fig2). More than half the incontinent respondents (91, 53.2%) and 245 (18.6%) of continent respondents reported bowel leakage due to an acute illness. There were no statistically significant gender, age or rurality differences for acute illness-related accidental bowel leakage.

A comparison of respondents with and without incontinence showed that more with incontinence reported poor or very poor general health; more frequent, irregular, incomplete/fragmented defecation, and looser stools; inability to delay by 15 minutes or requiring aids to defecate; alternating diarrhoea and constipation; a history of constipation; and pad-wearing (all $p<0.001$, Table 2). In addition, more incontinent respondents reported that their bowel function negatively affected their daily activities such as work, sports, housework/gardening, social activities, travel, relationships and sex life (all $p<0.001$). More than half the incontinent respondents (82/162) reported difficulty finding public toilets.

Embedded within the survey were a number of questions relating to accidental bowel leakage in addition to the Wexner score[5]. Table 1 presents the disclosure of accidental bowel leakage with the most severe element counted for each respondent. Those who did not report faecal incontinence, but disclosed accidental bowel leakage due to an acute illness, are reported separately in Table 1 ($n=245$, 97 male) even if they also reported other accidental bowel leakage items. Stool-related accidental bowel leakage (18.2%) included faecal incontinence, soiling with flatus (not including possible mucus-related soiling with flatus, $n=3$, one male), and soiling with urgency. This was not statistically different for gender or location/rurality of respondents' residences but was significantly higher for the over-40 age groups ($p=0.040$). Possible stool-related accidental bowel leakage (3.0%) included leakage of mucus; staining underwear, if it was considered a problem in the month prior to completing the survey; accidental bowel leakage that was found bothersome; and passive accidental bowel leakage. Of the remaining 1109/1513 respondents who completed these questions 346 (22.9%) reported they could not always differentiate between flatus and stool, 69 (4.6%) reported accidental leakage of flatus and only 532 (35.2%) respondents reported no concerns about accidental bowel leakage, and no accidental bowel leakage.

Types of accidental anal leakage are presented in Table 4 and did not differ across regions. Leakage rates of solid and liquid stool, mucus and accidental flatus were similar for both genders although staining of underwear was significantly higher in men (26.8%) than in women (17.3%, $p<0.001$) and for older respondents (<39: 15.9%; 40–59: 28.8%; >60: 33.7%, $p<0.001$).

Discussion

The main finding of this study was that 12.7% of adult North/Far North Queensland community members reported faecal incontinence in the previous 12 months that was not due to an acute illness. This rate increased with age for men although, in total, there were no gender or locality differences. When soiling with flatus and urgency were included, stool-related accidental bowel leakage was substantially higher, at 18.2%.

The prevalence of faecal incontinence is highly dependent on the definition applied[10,24]. This study's focused definition – 'accidental loss of solid and/or liquid stool in the previous twelve months, not due to a virus, medication or contaminated food' – has not, to the authors' knowledge, been used previously. Despite using this refined definition the rate of faecal incontinence in this study is higher than the two earlier Australian postal surveys[10,11] although the severity (type and frequency) was similar. Using a broader definition of accidental stool leakage that did not exclude faecal incontinence resulting from an acute illness, the prevalence was much higher, at 28.1% (Table 3). Thus previous concerns of high levels of faecal incontinence in the North/Far North Queensland community are warranted[3,12,13].

Table 1: Respondents' disclosure of accidental bowel leakage

Accidental bowel leakage[†]	Total[¶]	
	n	%
Faecal incontinence prevalence[§]	174	12.7
Soils with flatus[‡]	80	5.3
Soils with urgency	22	1.5
Stool-related	276	18.2
Leakage of mucus	10	0.7
Stains underwear[‖]	18	1.2
Finds accidental bowel leakage bothersome	11	0.7
Passive accidental bowel leakage	6	0.4
Possibly stool-related	45	3.0
Cannot always differentiate between flatus and stool	346	22.9
Flatus	69	4.6
Acute illness-related[#]	245	16.2
No accidental bowel leakage/concerns	532	35.2
Total	1513	

[†] In past 12 months not due to virus, medication or contaminated food (except acute illness related accidental bowel leakage – see note #).

[¶] Each respondent is counted once only (worst severity noted). Ten missing – respondents did not answer any of the questions about disclosure of accidental bowel leakage.

[§] Faecal incontinence (accidental solid and/or liquid leakage) in past 12 months not due to an acute illness; prevalence (95% confidence interval=12.7% (10.9–14.5%)) was based on response to Cleveland Clinic Florida-Fecal Incontinence Score (Wexner) questions only (*n*=1366, 572 men, 794 women).

[‡] Does not include possible mucus-related soiling with flatus (three: one man, two women).

[‖] In participants who have not disclosed faecal loss (solid/liquid/mucus) but whose staining of underwear was a problem in the month prior to survey completion.

[#] Participants who did not report faecal incontinence but reported accidental bowel leakage due to virus, medication or contaminated food included here whether or not they also reported any of the other stool, possible stool or flatus-related items.

Table 2: Comparison of bowel habits and health in respondents with and without faecal incontinence

	Faecal incontinence[†]		No faecal Incontinence[†]	
Bowel habits and health	*n*	%	*n*	%
Bowel movement at regular time	81/172	47.1	762/1243	61.3
Can always differentiate between flatus and stool	48/171	28.1	654/1222	53.5
Can delay bowel motion for 15 minutes	65/171	38.0	812/1222	66.4
Bowels open ≥2 times per day	72/171	42.1	312/1247	25.0
Difficulty completely emptying bowels	30/173	17.3	84/1240	6.8
Often/always repeats defecation within 1 hour	26/171	15.2	47/1225	3.8
Requires aids to defecate	48/164	29.3	96/1163	8.3
Mean stool type (range 1–7)[¶]	157	4.1	1199	3.8
Alternating diarrhoea/constipation	106/171	62.0	482/1225	39.3
Minutes spent defecating per day (5–60 max)	103/171	60.2	534/1240	43.1
Straining				
Frequency whilst defecating: often/always	23/171	13.5	64/1243	5.1
Strength: somewhat/very hard	55/170	32.4	239/1240	19.3
Duration: ≤ 1 minute	106/170	62.4	952/1237	77.0
No pain with bowel movement	74/172	43.0	781/1250	62.5
History of constipation	58/170	34.1	168/1314	12.8
Uses pad for protection (day and/or night)	30/155	19.4	14/1170	1.2
Poor/very poor general health	17/173	9.8	29/1245	2.3

[†] $p<0.001$. Classic χ^2 except for Mean Bristol Stool Form Scale (student's *t*-test).

[¶] Bristol Stool Form Scale; respondents who reported multiple or varied types of stool passed were removed (11 with, 25 without faecal incontinence).

Table 3: Frequency of accidental faecal leakage in respondents[†]

Leakage disclosed	*n*	%	95%CI (%)
Faecal incontinence[¶]			
Always (≥ 1 per day)	2/1369	0.1	0.0–0.3
Usually (≥1 per week and <1 per day)	10/1369	0.7	0.3–1.2
Sometimes (≥1 per month and <1 per week)	32/1369	2.3	1.5–3.1
Rarely (less than once per month)	130/1369	9.5	7.9–11.1
Total	174/1369		
Accidental soiling with acute illness[§,‡]	336/1482	22.7	20.5–24.8
>5 times annually[‖]	8/1311	0.6	0.2–1.0
3–5 times annually[‖]	15/1311	1.1	0.6–1.7
1–2 times annually[‖]	222/1311	16.9	14.9–19.0
Faecal incontinence, or accidental soiling due to acute illness	419/1493	28.1	25.8–30.4
No faecal leakage	1074/1493	71.9	69.7–74.2

[†] Greatest severity reported.
[¶] Faecal incontinence (accidental solid and/or liquid leakage) in past 12 months not due to a virus, medication or spoiled food.
[§] Accidental loss of solid and/or liquid stool in the previous 12 months, due to a virus, medication or contaminated food.
[‡] Includes those who did and did not disclose faecal incontinence.
[‖] Includes only those who did not disclose faecal incontinence.

Table 4: Accidental anal leakage in respondents[†]

Type of leakage	*n*	%[¶]	95%CI (%)
Solid[§]	47/1320	3.6	2.6–4.6
Liquid[§]	147/1345	10.9	9.2–12.6
Mucus	63/1301	4.8	3.7–6.0
Staining[‡]	273/1286	21.2	18.9–23.4
Any above	467/1487	31.4	29.0–33.7
Flatus[§]	347/1348	25.7	23.4–28.0

[†] Anal leakage in 12 months prior to survey.
[¶] Prevalence and 95% confidence interval.
[§] Cleveland Clinic Florida – Fecal Incontinence Score.
[‡] In participants who have not disclosed faecal loss (solid/liquid/mucus) but who currently soil clothing while passing wind and/or where staining of underwear was a problem in the month prior to survey completion.

One strength of this survey was that it enabled respondents to disclose any type of accidental bowel leakage, whether they termed it faecal incontinence or not. In a recent New Zealand study, researchers combined three different measures – a bowel control problem, quality of life impairment and faecal incontinence ≥1/month – to better determine faecal incontinence prevalence in the community[25]. While the researchers reported 12.4% of respondents leaked solid or liquid stool at least once per month and 26.8% had impaired quality of life due to accidental bowel leakage, they calculated community prevalence at 13.2% using the overlap of at least two of three measures to redefine faecal incontinence. The aim of the present study too was to provide a more accurate estimate of those suffering with faecal incontinence. In this study, issues such as flatus and mucus were excluded. The New Zealand survey tool may have included these in the quality of life component[26], thereby overstating the prevalence. Up to 50% of studies previously reviewed[8,24] calculated prevalence using faecal incontinence occurring in the previous 12 months as done in the present study. As in those studies, the rate in this study may be higher than that of the New Zealand study and others using incontinence reported over shorter time frames.

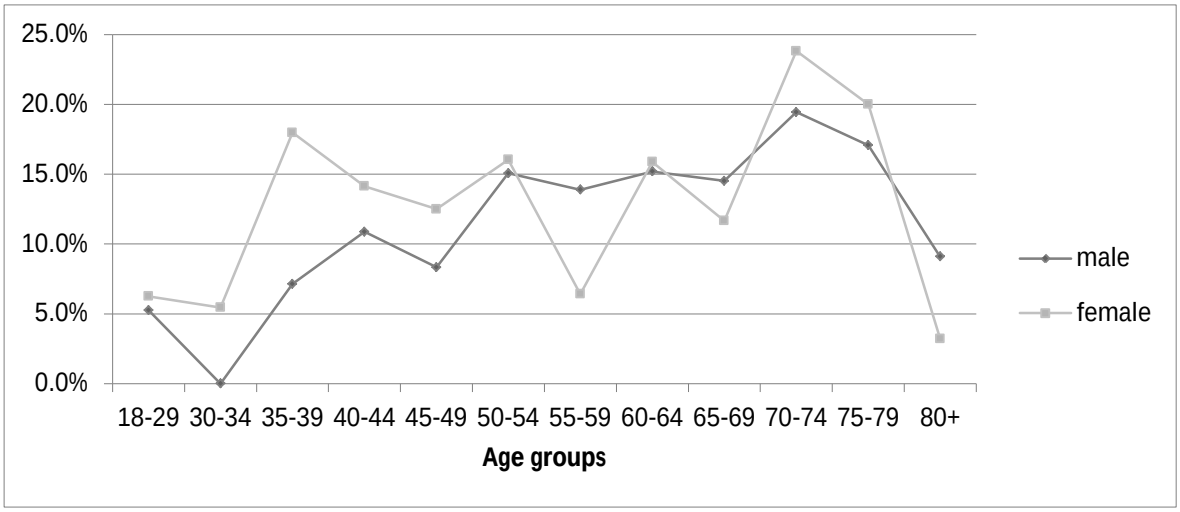
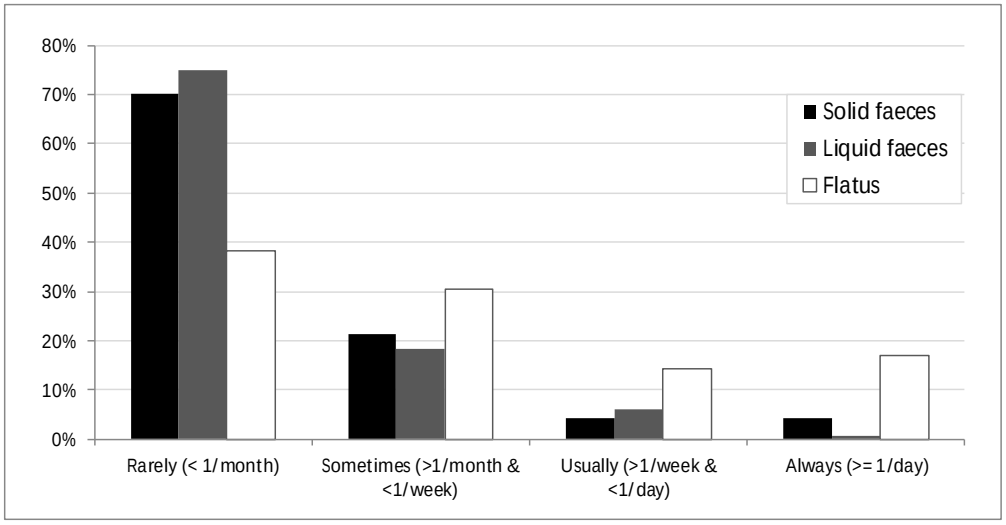


Figure 1: Proportion of respondents with faecal incontinence.



† Anal incontinence (accidental solid, liquid or flatus leakage) in past 12 months not due to virus/medication/contaminated food, from data collected in Cleveland Clinic Florida Fecal Incontinence questions.

Figure 2: Frequency of anal leakage† in respondents with faecal incontinence

A troubling result is that only 35% of the respondents had no bowel concerns. Further, many respondents with faecal incontinence felt they had no control over their bowels and didn't know how to manage their diet or which medications to take to mitigate the problem. As only 7% actually sought medical advice, fear, embarrassment and the stigma associated with faecal incontinence continues to hamper disclosure as previously identified[27].

As more people age 'in place'[16] the prevalence of faecal incontinence in the community is likely to increase toward that of aged-care facilities. Younger cohorts, which are less stoic, are unlikely to tolerate this condition and will demand treatment[17,20]. Ageing populations increase healthcare costs[15], and increased demand for faecal incontinence treatment will further escalate these costs. The concepts of the Ottawa Charter for Health Promotion[21] can be used to help reduce this added financial burden by encouraging prevention of constipation and obstetric damage, and ensuring benign clinical diagnoses are managed with conservative programs (potentially self-managed) including dietary management, pelvic floor exercises, defecation and relaxation techniques, and home biofeedback[28].

Limitations of this study include a low response rate of 48.1% despite mailing two follow-up questionnaires. The average age of survey respondents was 54 years, 9 years older than the North/Far North Queensland adult population (45 years), which is marginally younger than the state (46 years) and national (46.5 years) averages[29]. Reasons for the low response rate could include lack of interest in the subject matter, particularly among younger survey recipients. Furthermore, younger people may be under-represented, not only because they may have chosen not to respond to the questionnaire, but also because they are more likely to only have a mobile telephone and thus not have received a survey because they were not listed in the telephone directory[30]. Older respondents may have self-selected due to a particular interest in the topic or because of a personal bowel issue[24]. Townsville, the largest city in North Queensland, has a highly mobile population with a 35% net transient population measure[31]. Of the sample of 100 non-respondents telephoned in an attempt to further increase the response rate, 14 telephones had been disconnected. If this were representative of the population, it could also partially explain the low response rate. However, using the alternative data collection method of telephone interviews may have yielded an even lower response rate based on experience from the South Australian study[9]. Similar response rates using this or analogous study enrolment methods were found in a cross-sectional study investigating accidents and injuries in North Queensland[32] and a New Zealand faecal incontinence prevalence study using a random selection from the Canterbury electoral roll[33]. Thus the response rate may be a limitation of the method used to elicit information about a topic that is either 'sensitive' or does not interest a particular segment of the population.

Conclusions

There is a high level of untreated faecal incontinence in the North/Far North Queensland community which degrades the quality of life of those with this ailment. With a burgeoning ageing-in-place population the prevalence in this and other communities is likely to increase. Lifestyle education to prevent chronic constipation and encourage the development and maintenance of strong pelvic floor muscles among young people could reduce the prevalence of this condition. Faecal incontinence, its prevalence, prevention and treatments should be widely discussed to raise community awareness reducing the incidence and the destructive effect it has on the quality of so many lives. Eliminating the stigma of faecal incontinence should encourage those with the condition to overcome their embarrassment and seek early treatment. Where appropriate, conservative self-managed care is economically rational and can improve quality of life for all, not just those with access to the few specialist biofeedback clinics.

References

1. Whitehead WE. Diagnosing and managing fecal incontinence: if you don't ask, they won't tell. *Gastroenterology* 2005; 129: 6.

2. Norton C, Whitehead W, Bliss D, Metsola P, Tries J. Conservative treatment and pharmacological management of faecal incontinence in adults. In: A Abrams, L Cardozo, S Khoury, A Wein (Eds). *Incontinence*. Paris: International Continence Society, 2005; 1521-1564.

3. Bartlett L, Nowak M, Ho YH. Impact of fecal incontinence on quality of life. *World Journal of Gastroenterology* 2009; **15:** 3276-3282.

4. Bliss DZ, Norton C, Vodusek DB. Raising awareness about fecal incontinence. *Neurology and Urodynamics* 2010; **29:** 612-615.

5. Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Diseases of the Colon and Rectum* 1993; **36:** 77-97.

6. Norton C, Chelvanayagam S. Causes of faecal incontinence. In: C Norton, S Chelvanayagam, (Eds). *Bowel continence nursing*. Beaconsfield, Buckinghamshire: Beaconsfield Publishers Ltd, 2004; 23-32.

7. 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):** 512-517.

8. Pretlove SJ, Radley S, Toozs-Hobson PM, Thompson PJ, Coomarasamy A, Khan KS. Prevalence of anal incontinence according to age and gender: a systematic review and meta-regression analysis. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2006; **17:** 407-417.

9. Hawthorne G. *Measuring Incontinence in Australia*. (Online). 2006. Available: http://www.bladderbowel.gov.au/assets/doc/ncms/Phase1-2InformationAndEvidence/14OutcomesMeasuresTrialSAHOSpdf (Accessed 24 October 2012).

10. Kalantar JS, Howell S, Talley NJ. Prevalence of faecal incontinence and associated risk factors; an underdiagnosed problem in the Australian community? *Medical Journal of Australia* 2002; **176:** 54-57.

11. Lam TCF, Kennedy ML, Chen FC, Lubowski D, Talley NJ. Prevalence of faecal incontinence: obstetric and constipation risk factors: a population based study. *Colorectal Disease* 1999; **1:** 197-203.

12. Ho YH, Muller R, Veitch C, Rane A, Durrheim D. Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. *Australian Journal of Rural Health* 2005; **13:** 28-34.

13. Bartlett L, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Techniques in Coloproctology* 2007; **11:** 251-257.

14. Australian Institute of Health and Welfare (AIHW). *Australian incontinence data analysis and development*. AIHW cat no. DIS 44, 2006; 119.

15. Productivity Commission (2008). *Future demand for aged care services: trends in aged care services: some implications*. Commission research paper. Canberra, ACT: Australian Government.

16. Australian Institute of Health and Welfare (AIHW). *The desire to age in place among older Australians volume 1 – reasons for staying or moving*. AIHW bulletin. Cat. no. AUS 169, 2013.

17. Berkowitz EN, Schewe CD. Generational cohorts hold the key to understanding patients and health care providers: coming-of-age experiences influence health care behaviors for a lifetime. *Health Marketing Quarterly* 2011; **28:** 190-204.

18. Bartlett L, Ho YH. PTQ™ anal implants for the treatment of faecal incontinence. *British Journal of Surgery* 2009; **96:** 1468-1475.

19. Maeda Y, O'Connell PR, Matzel KE, Laurberg S. Sacral nerve stimulation for fecal incontinence: at a crossroad and future challenges. *Diseases of the Colon and Rectum* 2012; **55:** 621-624.

20. Keckley P. *2010 Survey of Health Care Consumers: key findings, strategic implications*. (Online). 2010. Available: http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/US_CHS_2010SurveyofHealthCareConsumers_050310.pdf (Accessed 5 September 2012).

21. World Health Organization (WHO). *The Ottawa Charter for Health Promotion*. (Online). http://www.who.int/healthpromotion/conferences/previous/ottawa/en (Accessed 28 October 2013)

22. Lewis SJ, Heaton KW. Stool form scale as a useful guide to intestinal transit time. *Scandinavian Journal of Gastroenterology* 1997; **32:** 920-924.

23. Fallon A, Westaway J, Moloney C. A systematic review of psychometric evidence and expert opinion regarding the assessment of faecal incontinence in older community-dwelling adults. *International Journal of Evidence-based Healthcare* 2008; 6: 225-259.

24. Macmillan AK, Merrie AE, Marshall RJ, Parry BR. The prevalence of fecal incontinence in community-dwelling adults: a systematic review of the literature. *Diseases of the Colon and Rectum* 2004; 47: 1341-1349.

25. Sharma A, Marshall RJ, Macmillan AK, Merrie AE, Reid P, Bissett IP. Determining levels of fecal incontinence in the community: a New Zealand cross-sectional study. *Diseases of the Colon and Rectum* 2011; 54: 1381-1387.

26. Macmillan AK, Merrie AE, Marshall RJ, Parry BR. Design and validation of a comprehensive fecal incontinence questionnaire. *Diseases of the Colon and Rectum* 2008; 51: 1502-1522.

27. Bartlett L, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Techniques in Coloproctology* 2007; 11: 251-257.

28. Bartlett LM, Sloots K, Nowak M, Ho YH. Biofeedback therapy for faecal incontinence: a rural and regional perspective. *Rural Remote Health* 11(1): 1630. (Online) 2011. Available: www.rrh.org.au (Accessed 24 October 2013).

29. Australian Bureau of Statistics. *Population by age and sex, Australian states and territories, June 2010*. ABS cat. no. 3201.0, 2010.

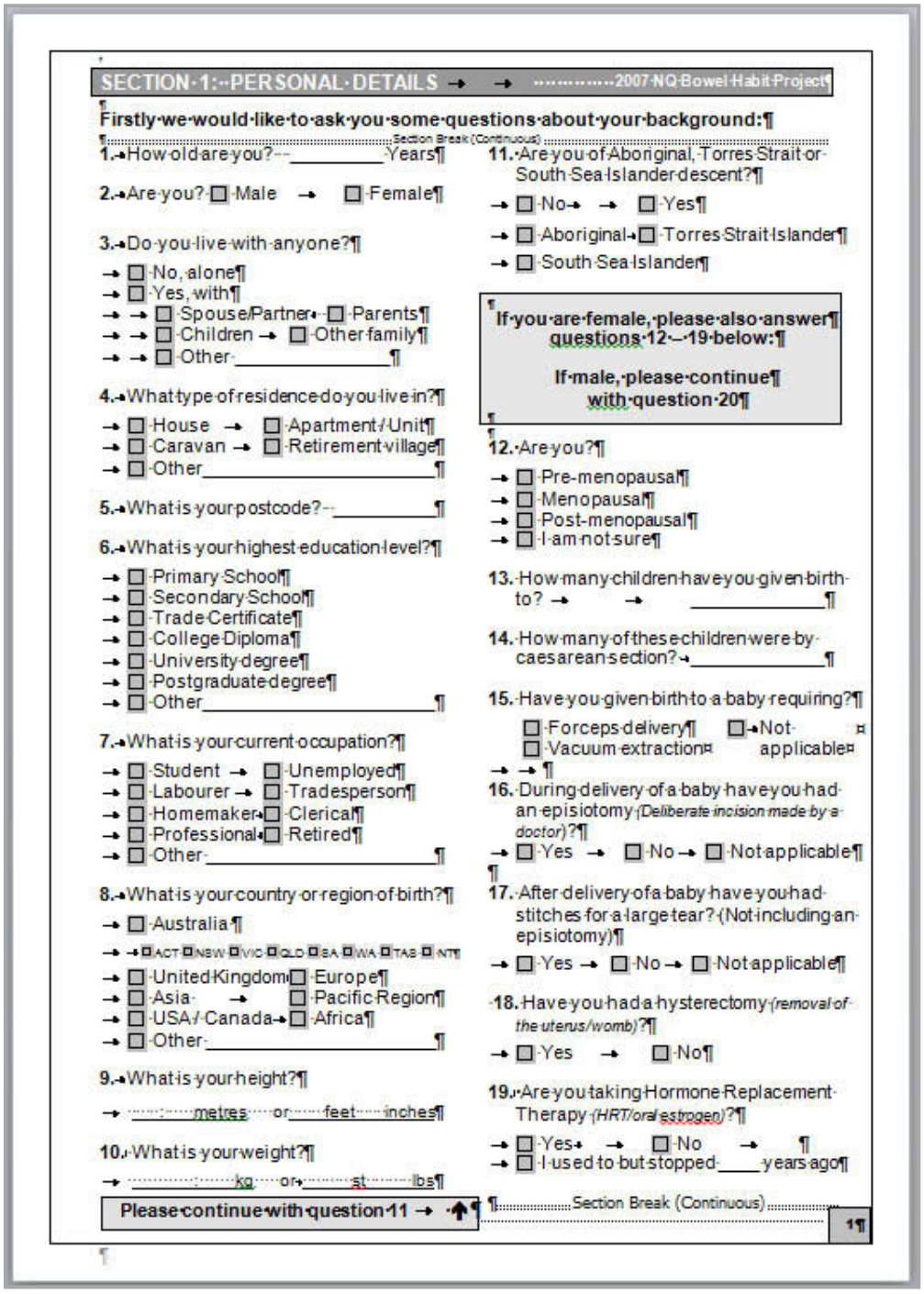
30. Call K, Davern M, Boudreaux M, Johnson P, Nelson J. Bias in telephone surveys that do not sample cell phones: uses and limits of poststratification adjustments. *Medical Care* 2011; 49: 355-364.

31. Cummings Economics. Comparative transient populations in Australian cities. (Online) 2011. Available: http://www.cummings.net.au/pdf/recent/J2276%20CE%20Note%20Comp%20Trans%20Pop'n%20Levels.pdf (Accessed 15 August 2011).

32. Carter A, Muller R. Practices, knowledge and perceptions influencing accident and injury in the Mackay/Whitsunday community. In: *Reducing injuries in Mackay, North Queensland*. Warwick, Queensland: Warwick Educational Publishing, 2002; 53-73.

33. Lynch AC, Dobbs BR, Keating J, Frizelle FA. The prevalence of faecal incontinence and constipation in a general New Zealand population; a postal survey. *New Zealand Medical Journal* 2001; 114: 474-477.

Appendix 1: North Queensland Bowel Habit Project Survey



SECTION 1: PERSONAL DETAILS → 2007 NQ Bowel Habit Project

Firstly we would like to ask you some questions about your background:

Section Break (Continuous)

1. How old are you? _____ Years

2. Are you? ☐ Male → ☐ Female

3. Do you live with anyone?
→ ☐ No, alone
→ ☐ Yes, with
→ → ☐ Spouse/Partner ☐ Parents
→ → ☐ Children → ☐ Other family
→ → ☐ Other _____

4. What type of residence do you live in?
→ ☐ House → ☐ Apartment / Unit
→ ☐ Caravan → ☐ Retirement village
→ ☐ Other _____

5. What is your postcode? _____

6. What is your highest education level?
→ ☐ Primary School
→ ☐ Secondary School
→ ☐ Trade Certificate
→ ☐ College Diploma
→ ☐ University degree
→ ☐ Postgraduate degree
→ ☐ Other _____

7. What is your current occupation?
→ ☐ Student → ☐ Unemployed
→ ☐ Labourer → ☐ Tradesperson
→ ☐ Homemaker → ☐ Clerical
→ ☐ Professional → ☐ Retired
→ ☐ Other _____

8. What is your country or region of birth?
→ ☐ Australia
→ → ☐ ACT ☐ NSW ☐ VIC ☐ QLD ☐ SA ☐ WA ☐ TAS ☐ NT
→ ☐ United Kingdom ☐ Europe
→ ☐ Asia → ☐ Pacific Region
→ ☐ USA / Canada → ☐ Africa
→ ☐ Other _____

9. What is your height?
→ _____ metres or _____ feet _____ inches

10. What is your weight?
→ _____ kg or _____ st _____ lbs

Please continue with question 11 →

11. Are you of Aboriginal, Torres Strait or South Sea Islander descent?
→ ☐ No → → ☐ Yes
→ ☐ Aboriginal ☐ Torres Strait Islander
→ ☐ South Sea Islander

If you are female, please also answer questions 12 – 19 below:

If male, please continue with question 20

12. Are you?
→ ☐ Pre-menopausal
→ ☐ Menopausal
→ ☐ Post-menopausal
→ ☐ I am not sure

13. How many children have you given birth to? → → _____

14. How many of these children were by caesarean section? → _____

15. Have you given birth to a baby requiring?
☐ Forceps delivery ☐ Not applicable
☐ Vacuum extraction
→ →

16. During delivery of a baby have you had an episiotomy *(Deliberate incision made by a doctor)*?
→ ☐ Yes → ☐ No → ☐ Not applicable

17. After delivery of a baby have you had stitches for a large tear? (Not including an episiotomy)
→ ☐ Yes → ☐ No → ☐ Not applicable

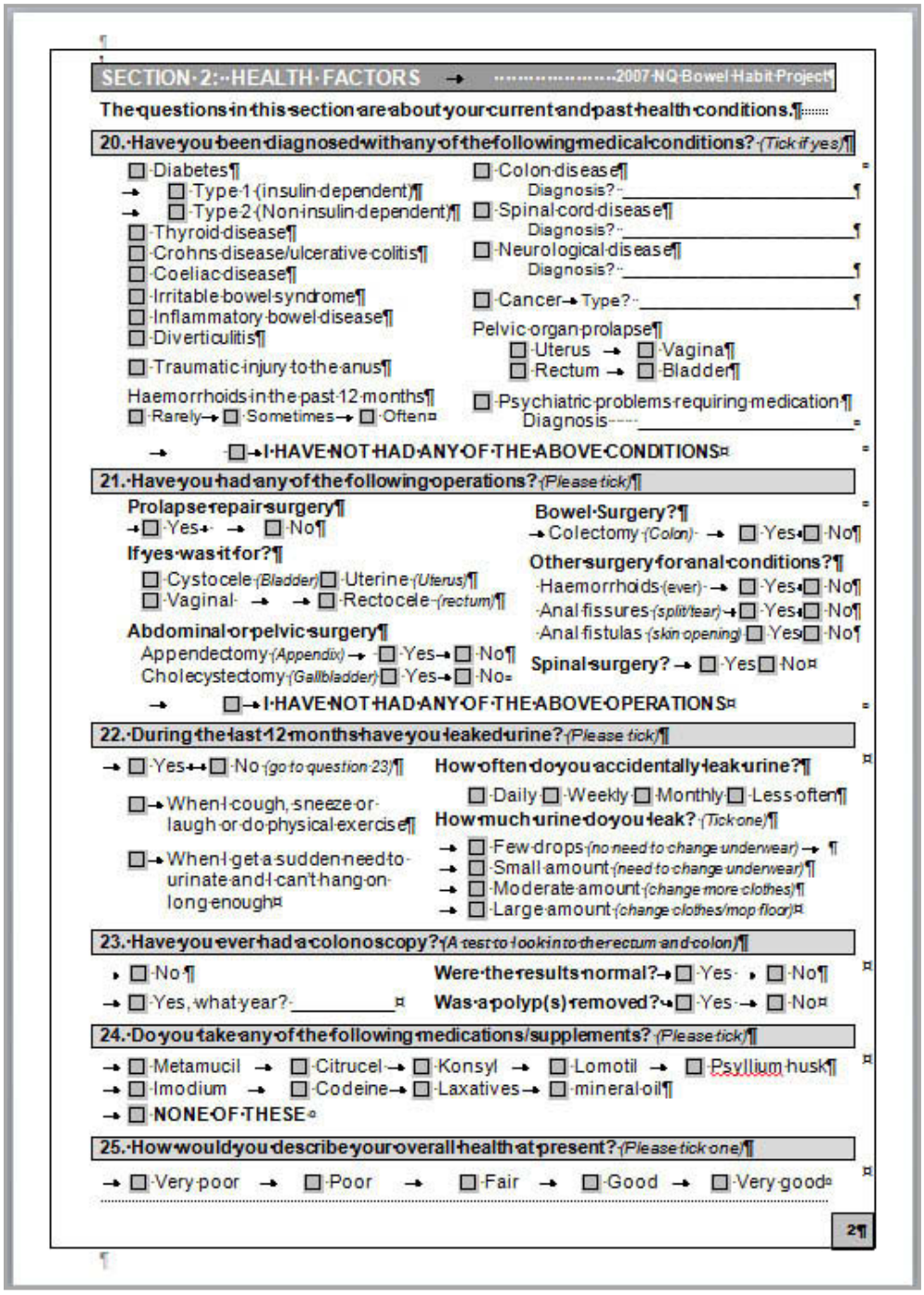
18. Have you had a hysterectomy *(removal of the uterus/womb)*?
→ ☐ Yes → ☐ No

19. Are you taking Hormone Replacement Therapy *(HRT/oral estrogen)*?
→ ☐ Yes → → ☐ No →
→ ☐ I used to but stopped _____ years ago

Section Break (Continuous)

1

Appendix 1: North Queensland Bowel Habit Project Survey: cont'd



SECTION 2: HEALTH FACTORS → ..... 2007 NQ Bowel Habit Project

The questions in this section are about your current and past health conditions.

20. Have you been diagnosed with any of the following medical conditions? *(Tick if yes)*

- ☐ Diabetes
  - → ☐ Type 1 (insulin dependent)
  - → ☐ Type 2 (Non-insulin dependent)
- ☐ Thyroid disease
- ☐ Crohns disease/ulcerative colitis
- ☐ Coeliac disease
- ☐ Irritable bowel syndrome
- ☐ Inflammatory bowel disease
- ☐ Diverticulitis
- ☐ Traumatic injury to the anus
- Haemorrhoids in the past 12 months
  - ☐ Rarely → ☐ Sometimes → ☐ Often
- ☐ Colon disease — Diagnosis? _____
- ☐ Spinal cord disease — Diagnosis? _____
- ☐ Neurological disease — Diagnosis? _____
- ☐ Cancer → Type? _____
- Pelvic organ prolapse
  - ☐ Uterus → ☐ Vagina
  - ☐ Rectum → ☐ Bladder
- ☐ Psychiatric problems requiring medication — Diagnosis _____

→ ☐ → **I HAVE NOT HAD ANY OF THE ABOVE CONDITIONS**

21. Have you had any of the following operations? *(Please tick)*

Prolapse repair surgery
→ ☐ Yes → ☐ No

If yes was it for?
- ☐ Cystocele *(Bladder)* ☐ Uterine *(Uterus)*
- ☐ Vaginal → → ☐ Rectocele *(rectum)*

Abdominal or pelvic surgery
- Appendectomy *(Appendix)* → ☐ Yes → ☐ No
- Cholecystectomy *(Gallbladder)* ☐ Yes → ☐ No

Bowel Surgery?
→ Colectomy *(Colon)* → ☐ Yes ☐ No

Other surgery for anal conditions?
- Haemorrhoids *(ever)* → ☐ Yes ☐ No
- Anal fissures *(split/tear)* → ☐ Yes ☐ No
- Anal fistulas *(skin opening)* ☐ Yes ☐ No

Spinal surgery? → ☐ Yes ☐ No

→ ☐ → **I HAVE NOT HAD ANY OF THE ABOVE OPERATIONS**

22. During the last 12 months have you leaked urine? *(Please tick)*

→ ☐ Yes ↔ ☐ No *(go to question 23)*

- ☐ → When I cough, sneeze or laugh or do physical exercise
- ☐ → When I get a sudden need to urinate and I can't hang on long enough

How often do you accidentally leak urine?
☐ Daily ☐ Weekly ☐ Monthly ☐ Less often

How much urine do you leak? *(Tick one)*
- → ☐ Few drops *(no need to change underwear)* →
- → ☐ Small amount *(need to change underwear)*
- → ☐ Moderate amount *(change more clothes)*
- → ☐ Large amount *(change clothes/mop floor)*

23. Have you ever had a colonoscopy? *(A test to look in to the rectum and colon)*

- → ☐ No
- → ☐ Yes, what year? _____

Were the results normal? → ☐ Yes → ☐ No

Was a polyp(s) removed? → ☐ Yes → ☐ No

24. Do you take any of the following medications/supplements? *(Please tick)*

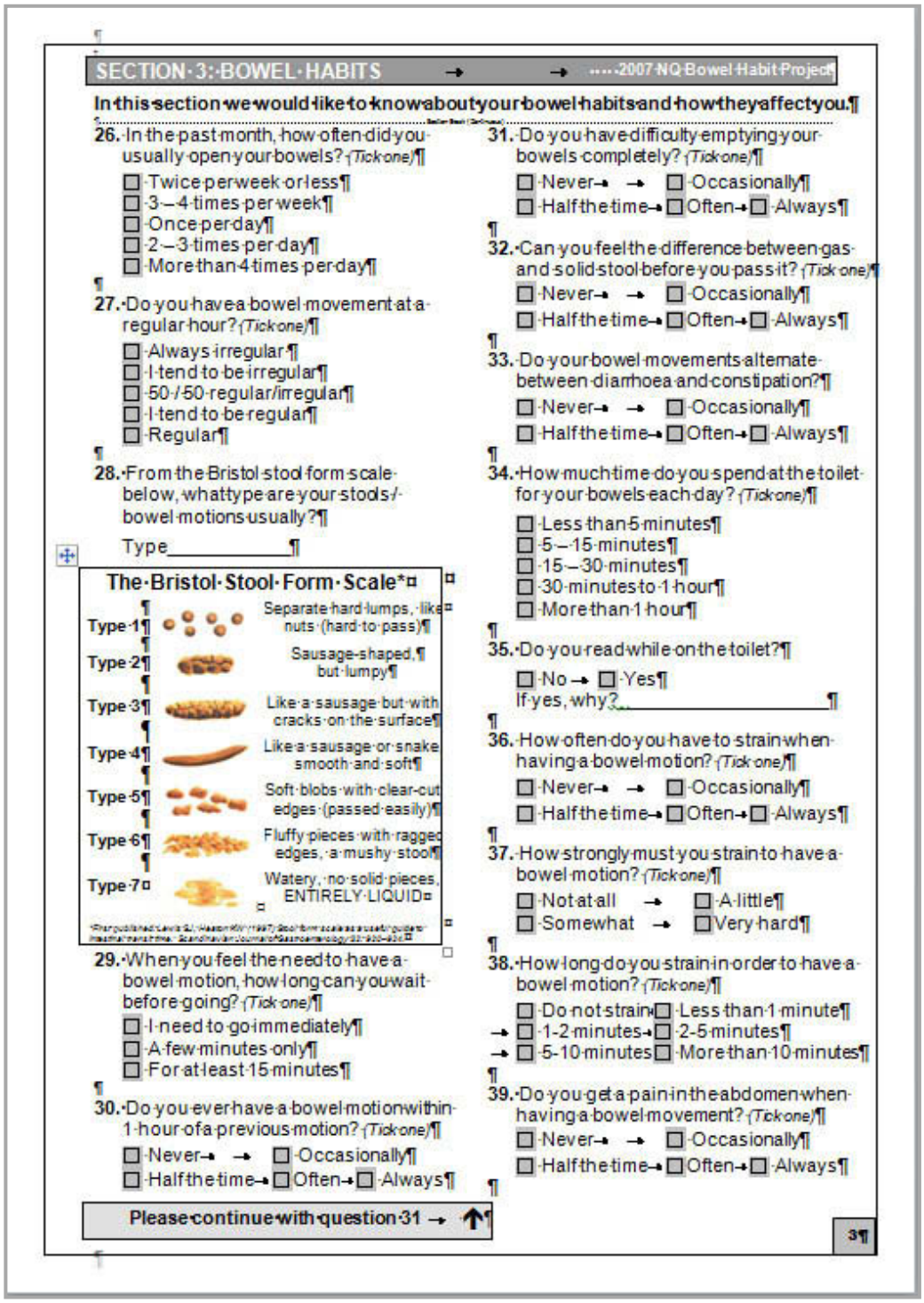
- → ☐ Metamucil → ☐ Citrucel → ☐ Konsyl → ☐ Lomotil → ☐ Psyllium husk
- → ☐ Imodium → ☐ Codeine → ☐ Laxatives → ☐ mineral oil
- → ☐ **NONE OF THESE**

25. How would you describe your overall health at present? *(Please tick one)*

→ ☐ Very poor → ☐ Poor → ☐ Fair → ☐ Good → ☐ Very good

2

Appendix 1: North Queensland Bowel Habit Project Survey: cont'd



SECTION 3: BOWEL HABITS → → ····2007 NQ Bowel Habit Project

In this section we would like to know about your bowel habits and how they affect you.

26. In the past month, how often did you usually open your bowels? *(Tick one)*

- ☐ Twice per week or less
- ☐ 3 – 4 times per week
- ☐ Once per day
- ☐ 2 – 3 times per day
- ☐ More than 4 times per day

27. Do you have a bowel movement at a regular hour? *(Tick one)*

- ☐ Always irregular
- ☐ I tend to be irregular
- ☐ 50 / 50 regular/irregular
- ☐ I tend to be regular
- ☐ Regular

28. From the Bristol stool form scale below, what type are your stools / bowel motions usually?

Type _____

The Bristol Stool Form Scale*

Type 1	Separate hard lumps, like nuts (hard to pass)
Type 2	Sausage-shaped, but lumpy
Type 3	Like a sausage but with cracks on the surface
Type 4	Like a sausage or snake, smooth and soft
Type 5	Soft blobs with clear-cut edges (passed easily)
Type 6	Fluffy pieces with ragged edges, a mushy stool
Type 7	Watery, no solid pieces, ENTIRELY LIQUID

*Par publiée Lewis SJ, Heaton KW (1997) Stool form scale as a useful guide to intestinal transit time. Scandinavian Journal of Gastroenterology 32: 920–924.

29. When you feel the need to have a bowel motion, how long can you wait before going? *(Tick one)*

- ☐ I need to go immediately
- ☐ A few minutes only
- ☐ For at least 15 minutes

30. Do you ever have a bowel motion within 1 hour of a previous motion? *(Tick one)*

- ☐ Never → ☐ Occasionally
- ☐ Half the time → ☐ Often → ☐ Always

Please continue with question 31 →

31. Do you have difficulty emptying your bowels completely? *(Tick one)*

- ☐ Never → ☐ Occasionally
- ☐ Half the time → ☐ Often → ☐ Always

32. Can you feel the difference between gas and solid stool before you pass it? *(Tick one)*

- ☐ Never → ☐ Occasionally
- ☐ Half the time → ☐ Often → ☐ Always

33. Do your bowel movements alternate between diarrhoea and constipation?

- ☐ Never → ☐ Occasionally
- ☐ Half the time → ☐ Often → ☐ Always

34. How much time do you spend at the toilet for your bowels each day? *(Tick one)*

- ☐ Less than 5 minutes
- ☐ 5 – 15 minutes
- ☐ 15 – 30 minutes
- ☐ 30 minutes to 1 hour
- ☐ More than 1 hour

35. Do you read while on the toilet?

- ☐ No → ☐ Yes

If yes, why? _____

36. How often do you have to strain when having a bowel motion? *(Tick one)*

- ☐ Never → ☐ Occasionally
- ☐ Half the time → ☐ Often → ☐ Always

37. How strongly must you strain to have a bowel motion? *(Tick one)*

- ☐ Not at all → ☐ A little
- ☐ Somewhat → ☐ Very hard

38. How long do you strain in order to have a bowel motion? *(Tick one)*

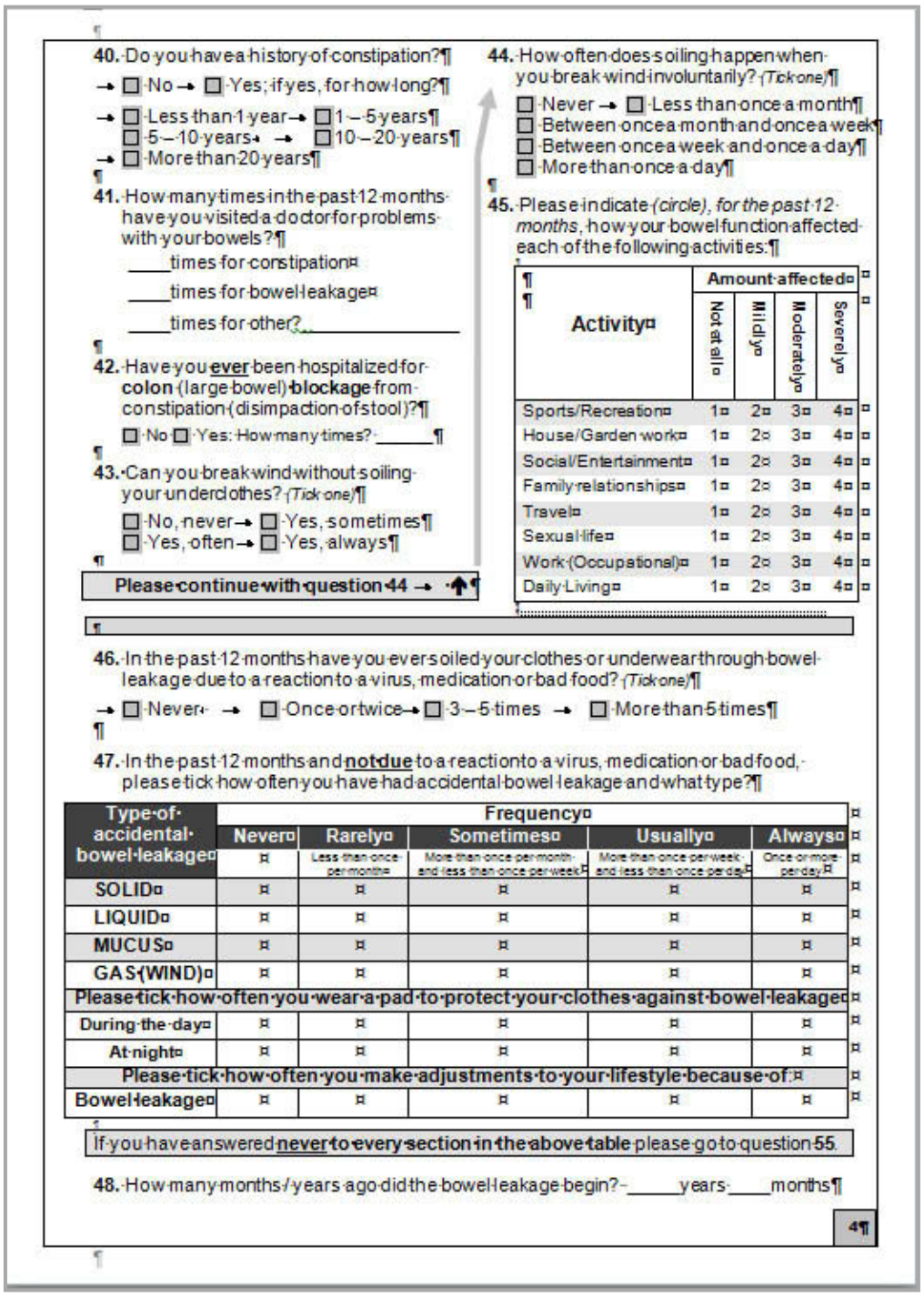
- ☐ Do not strain ☐ Less than 1 minute
- → ☐ 1-2 minutes ☐ 2-5 minutes
- → ☐ 5-10 minutes ☐ More than 10 minutes

39. Do you get a pain in the abdomen when having a bowel movement? *(Tick one)*

- ☐ Never → ☐ Occasionally
- ☐ Half the time → ☐ Often → ☐ Always

3

Appendix 1: North Queensland Bowel Habit Project Survey: cont'd



40. Do you have a history of constipation?
→ ☐ No → ☐ Yes; if yes, for how long?
→ ☐ Less than 1 year → ☐ 1 – 5 years
☐ 5 – 10 years → ☐ 10 – 20 years
→ ☐ More than 20 years

41. How many times in the past 12 months have you visited a doctor for problems with your bowels?
____ times for constipation
____ times for bowel leakage
____ times for other? _____

42. Have you **ever** been hospitalized for **colon** (large bowel) **blockage** from constipation (disimpaction of stool)?
☐ No ☐ Yes: How many times? _____

43. Can you break wind without soiling your underclothes? *(Tick one)*
☐ No, never → ☐ Yes, sometimes
☐ Yes, often → ☐ Yes, always

Please continue with question 44 →

44. How often does soiling happen when you break wind involuntarily? *(Tick one)*
☐ Never → ☐ Less than once a month
☐ Between once a month and once a week
☐ Between once a week and once a day
☐ More than once a day

45. Please indicate *(circle), for the past 12 months*, how your bowel function affected each of the following activities:

Activity	Amount affected: Not at all	Mildly	Moderately	Severely
Sports/Recreation	1	2	3	4
House/Garden work	1	2	3	4
Social/Entertainment	1	2	3	4
Family relationships	1	2	3	4
Travel	1	2	3	4
Sexual life	1	2	3	4
Work (Occupational)	1	2	3	4
Daily Living	1	2	3	4

46. In the past 12 months have you ever soiled your clothes or underwear through bowel leakage due to a reaction to a virus, medication or bad food? *(Tick one)*
→ ☐ Never → ☐ Once or twice → ☐ 3 – 5 times → ☐ More than 5 times

47. In the past 12 months and **not due** to a reaction to a virus, medication or bad food, please tick how often you have had accidental bowel leakage and what type?

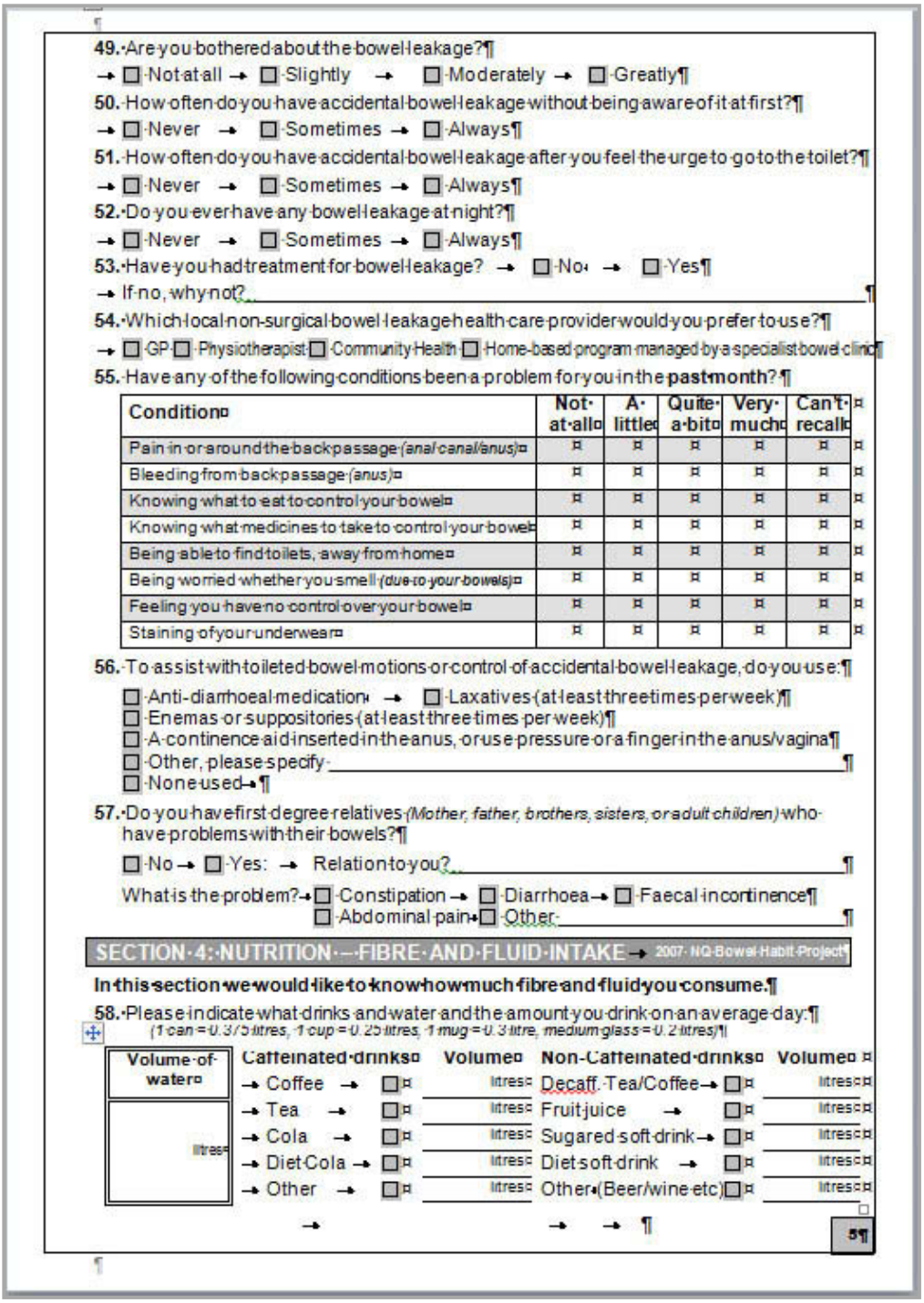
Type of accidental bowel leakage	Frequency: Never	Rarely: Less than once per month	Sometimes: More than once per month and less than once per week	Usually: More than once per week and less than once per day	Always: Once or more per day
SOLID					
LIQUID					
MUCUS					
GAS (WIND)					
Please tick how often you wear a pad to protect your clothes against bowel leakage					
During the day					
At night					
Please tick how often you make adjustments to your lifestyle because of:					
Bowel leakage					

If you have answered **never** to every section in the above table please go to question 55.

48. How many months / years ago did the bowel leakage begin? _____ years ____ months

4

Appendix 1: North Queensland Bowel Habit Project Survey: cont'd



49. Are you bothered about the bowel leakage?
→ ☐ Not at all → ☐ Slightly → ☐ Moderately → ☐ Greatly

50. How often do you have accidental bowel leakage without being aware of it at first?
→ ☐ Never → ☐ Sometimes → ☐ Always

51. How often do you have accidental bowel leakage after you feel the urge to go to the toilet?
→ ☐ Never → ☐ Sometimes → ☐ Always

52. Do you ever have any bowel leakage at night?
→ ☐ Never → ☐ Sometimes → ☐ Always

53. Have you had treatment for bowel leakage? → ☐ No → ☐ Yes
→ If no, why not? _____

54. Which local non-surgical bowel leakage health care provider would you prefer to use?
→ ☐ GP ☐ Physiotherapist ☐ Community Health ☐ Home-based program managed by a specialist bowel clinic

55. Have any of the following conditions been a problem for you in the **past month**?

Condition	Not at all	A little	Quite a bit	Very much	Can't recall
Pain in or around the back passage *(anal canal/anus)*					
Bleeding from back passage *(anus)*					
Knowing what to eat to control your bowel					
Knowing what medicines to take to control your bowel					
Being able to find toilets, away from home					
Being worried whether you smell *(due to your bowels)*					
Feeling you have no control over your bowel					
Staining of your underwear					

56. To assist with toileted bowel motions or control of accidental bowel leakage, do you use:
☐ Anti-diarrhoeal medication → ☐ Laxatives (at least three times per week)
☐ Enemas or suppositories (at least three times per week)
☐ A continence aid inserted in the anus, or use pressure or a finger in the anus/vagina
☐ Other, please specify _____
☐ None used →

57. Do you have first degree relatives *(Mother, father, brothers, sisters, or adult children)* who have problems with their bowels?
☐ No → ☐ Yes: → Relation to you? _____
What is the problem? → ☐ Constipation → ☐ Diarrhoea → ☐ Faecal incontinence
☐ Abdominal pain → ☐ Other: _____

SECTION 4: NUTRITION – FIBRE AND FLUID INTAKE → 2007 NQ Bowel Habit Project

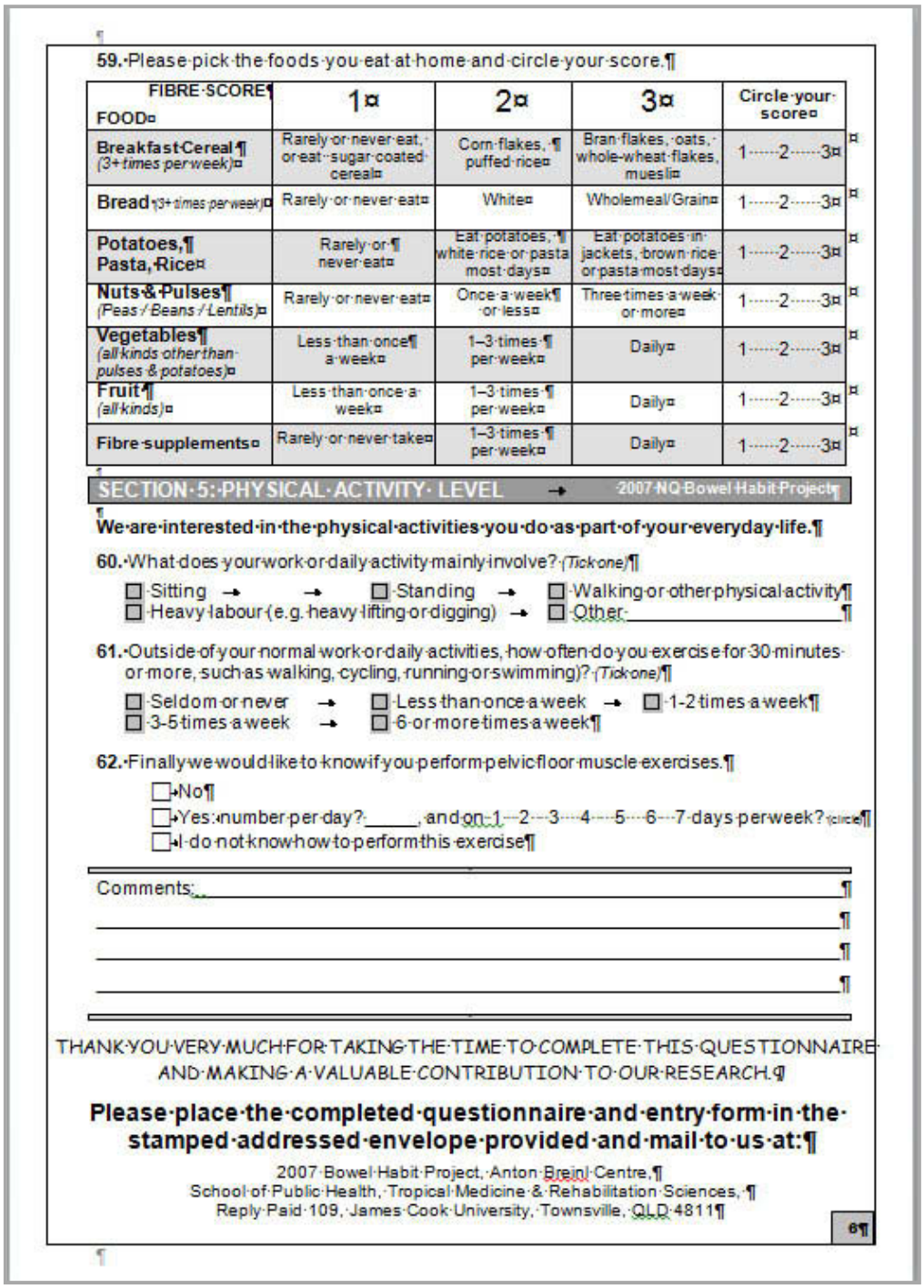
In this section we would like to know how much fibre and fluid you consume.

58. Please indicate what drinks and water and the amount you drink on an average day:
(1 can = 0.375 litres, 1 cup = 0.25 litres, 1 mug = 0.3 litre, medium glass = 0.2 litres)

Volume of water	litres	Caffeinated drinks		Volume	Non-Caffeinated drinks		Volume
		→ Coffee →	☐	litres	Decaff. Tea/Coffee →	☐	litres
		→ Tea →	☐	litres	Fruit juice →	☐	litres
		→ Cola →	☐	litres	Sugared soft drink →	☐	litres
		→ Diet Cola →	☐	litres	Diet soft drink →	☐	litres
		→ Other →	☐	litres	Other (Beer/wine etc)	☐	litres

→ → → 5

Appendix 1: North Queensland Bowel Habit Project Survey: cont'd



59. Please pick the foods you eat at home and circle your score.

FIBRE SCORE / FOOD	1	2	3	Circle your score
Breakfast Cereal *(3+ times per week)*	Rarely or never eat, or eat sugar coated cereal	Corn flakes, puffed rice	Bran flakes, oats, whole-wheat flakes, muesli	1 ----- 2 ----- 3
Bread *(3+ times per week)*	Rarely or never eat	White	Wholemeal/Grain	1 ----- 2 ----- 3
Potatoes, Pasta, Rice	Rarely or never eat	Eat potatoes, white rice or pasta most days	Eat potatoes in jackets, brown rice or pasta most days	1 ----- 2 ----- 3
Nuts & Pulses *(Peas / Beans / Lentils)*	Rarely or never eat	Once a week or less	Three times a week or more	1 ----- 2 ----- 3
Vegetables *(all kinds other than pulses & potatoes)*	Less than once a week	1–3 times per week	Daily	1 ----- 2 ----- 3
Fruit *(all kinds)*	Less than once a week	1–3 times per week	Daily	1 ----- 2 ----- 3
Fibre supplements	Rarely or never take	1–3 times per week	Daily	1 ----- 2 ----- 3

SECTION 5: PHYSICAL ACTIVITY LEVEL → 2007 NQ Bowel Habit Project

We are interested in the physical activities you do as part of your everyday life.

60. What does your work or daily activity mainly involve? *(Tick one)*

☐ Sitting → ☐ Standing → ☐ Walking or other physical activity
☐ Heavy labour (e.g. heavy lifting or digging) → ☐ Other: _____

61. Outside of your normal work or daily activities, how often do you exercise for 30 minutes or more, such as walking, cycling, running or swimming)? *(Tick one)*

☐ Seldom or never → ☐ Less than once a week → ☐ 1-2 times a week
☐ 3-5 times a week → ☐ 6 or more times a week

62. Finally we would like to know if you perform pelvic floor muscle exercises.

☐ No
☐ Yes: number per day? _____, and on 1 2 3 4 5 6 7 days per week? (circle)
☐ I do not know how to perform this exercise

Comments: _____

THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE AND MAKING A VALUABLE CONTRIBUTION TO OUR RESEARCH.

Please place the completed questionnaire and entry form in the stamped addressed envelope provided and mail to us at:

2007 Bowel Habit Project, Anton Breinl Centre,
School of Public Health, Tropical Medicine & Rehabilitation Sciences,
Reply Paid 109, James Cook University, Townsville, QLD 4811

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CHAPTER 4: QUALITY OF LIFE

Faecal incontinence can be measured in a number of ways: descriptively - present or absent, by severity (type and quantity) and by the effect on a person's wellbeing. Individuals' well-being is often evaluated in terms of their quality of life. Patients frequently describe faecal incontinence as a shameful and embarrassing condition which isolates them from their family and friends.

Common tools used to measure the impact of faecal incontinence on quality of life include the generic health surveys such as the SF-36 health survey questionnaire [1] and disease specific tools such as the Fecal Incontinence Quality of Life Scale [2], the Manchester Health Questionnaire (adapted from the urinary incontinence King's Health Questionnaire) [3, 4] and the TyPE specification, developed to measure fear of incontinence and activities affected by it [5]. Disease-specific quality of life measurement is extremely important because it includes aspects of disease which are not captured by generic quality-of-life measures [6].

In 2003 patients attending the urogynecology and colorectal outpatient clinics of the Townsville hospital were surveyed about the presence of faecal incontinence [7], and the impact of faecal incontinence on their quality of life was measured using the Fecal Incontinence Quality of Life Scale. This tool has 29 questions representing four domains of quality of life (lifestyle, coping-behaviour, depression, and embarrassment). This instrument has been extensively studies and found to be responsive to change, and to provide statistically significant improvements following conservative and surgical treatments for faecal incontinence [6]. In 2004 the study from 2003 was repeated (Chapter 2.1). As the self-administered survey tool was identical in both studies and there were no statistically significant differences in the Fecal Incontinence Quality of Life scales between the two studies, the data were combined and reported in the publication from this chapter: Bartlett et al, World Journal of Gastroenterology 2009.

Study aims:

- *To determine the effect of faecal incontinence on the quality of life of community-dwelling people with the condition in rural and regional North Queensland*

Publication arising from this chapter

4.1 Impact of faecal incontinence on quality of life

Bartlett L, Nowak M, Ho YH. Impact of fecal incontinence on quality of life. *World Journal of Gastroenterology*. 2009;15:3276-82

My estimated contribution was 88% (Contributors table, page xv)

References

1. Ware JE, Jr., Sherbourne CD, The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care*, 1992. 30(6): 473-83.

2. Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, Wexner SD, Bliss D, Lowry AC, Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Diseases of the Colon and Rectum* 2000. 43(1): 9-16.

3. Bugg GJ, Kiff ES, Hosker G, A new condition-specific health-related quality of life questionnaire for the assessment of women with anal incontinence. *BJOG : An International Journal of Obstetrics and Gynaecology*, 2001. 108(10): 1057-67.

4. Kelleher CJ, Cardozo LD, Khullar V, Salvatore S, A new questionnaire to assess the quality of life of urinary incontinent women. *British Journal of Obstetrics and Gynaecology*, 1997. 104(12): 1374-9.

5. Wexner SD, Baeten C, Bailey R, Bakka A, Belin B, Belliveau P, Berg E, Buie WD, Burnstein M, Christiansen J, Coller J, Galandiuk S, Lange J, Madoff R, Matzel KE, Pahlman L, Parc R, Reilly J, Seccia M, Thorson AG, Vernava AM, 3rd, Long-term efficacy of dynamic graciloplasty for fecal incontinence. *Diseases of the Colon and Rectum*, 2002. 45(6): 809-18.

6. Baxter NN, Rothenberger DA, Lowry AC, Measuring fecal incontinence. *Diseases of the Colon and Rectum* 2003. 46(12): 1591-605.

7. Ho YH, Muller R, Veitch C, Rane A, Durrheim D, Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. *Australian Journal of Rural Health*, 2005. 13(1): 28-34.

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BRIEF ARTICLES

Impact of fecal incontinence on quality of life

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Author contributions: Bartlett L and Ho YH designed the research; Bartlett L performed the research and analyzed the data; Bartlett L, Nowak M and Ho YH wrote the paper.
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Abstract

AIM: To explore the impact of fecal incontinence (FI) on quality of life (QOL) of patients attending urogynecology and colorectal clinics (CCs).

METHODS: Cross-sectional study of 154 patients (27 male) with FI, who attended the clinics at a regional hospital in North Queensland, Australia in 2003 and 2004, and completed the Fecal Incontinence Quality of Life Scale (FIQL: 1 = very affected; 4 = not affected).

RESULTS: More than 22% of patients had their QOL affected severely by FI. Patients reported that they had not previously been asked about FI by a medical practitioner nor did they voluntarily disclose its presence. The median FIQL scores for all participants were: lifestyle = 3.24; coping = 2.23; depression = 2.42; and embarrassment = 2.33. Increasing frequency of soiling had a negative effect on all four FIQL scales ($P < 0.001$) as did the quantity of soiling ($P < 0.01$). Female CC patients had poorer FIQL scores than urogynecology clinic patients for lifestyle ($P = 0.015$), coping ($P = 0.004$) and embarrassment ($P = 0.009$), but not depression ($P = 0.062$), despite having experienced FI for a shorter period.

CONCLUSION: Failure to seek treatment for FI degrades the quality of patients' lives over time. FI assessment tools should incorporate the quantity of fecal loss.

Key words: Quality of life; Fecal incontinence; Rural health; Colorectal cancer; Urogynecology

Peer reviewer: Dr. Giuseppe Chiarioni, Gastroenterological Rehabilitation Division of the University of Verona, Valeggio sul Mincio Hospital, Azienda Ospedale di Valeggio s/M, Valeggio s/M 37067, Italy

Bartlett L, Nowak M, Ho YH. Impact of fecal incontinence on quality of life. *World J Gastroenterol* 2009; 15(26): 3276-3282 Available from: URL: http://www.wjgnet.com/1007-9327/15/3276.asp DOI: http://dx.doi.org/10.3748/wjg.15.3276

INTRODUCTION

Fecal incontinence (FI) is the involuntary discharge of liquid or solid stools. FI severity has been described as a combination of the frequency and type of stools, the severity of urgency, and frequency of pad usage[1,2]. This problem affects both men and women, irrespective of social, employment or financial status[3,4]. The prevalence of FI increases with age[5,6] and Australian studies have reported some of the highest rates in the world[5,7,8].

People with mild fecal loss such as staining are unwilling to admit to themselves that they have an FI problem[9]. As the problem worsens and patients inevitably accept that they have FI, they are reluctant to disclose the problem to others[9-15], with only 5%-27% seeking help from their doctors[15]. Lack of disclosure may be to the result of embarrassment, the erroneous belief that FI is a normal part of aging, or the perception that no treatment is available. Doctors may fail to comprehend patient hints about diarrhea and FI[15] or may be reluctant to ask about fecal leakage, perhaps because of their own embarrassment or the perception that FI is a trivial concern[16].

FI can range from causing mild embarrassment to becoming an insidious burden on the person's quality of life (QOL)[17-21]. Tools used to measure the impact of FI on QOL have been under development for 20 years and include lifestyle components in summary scales, generic measures, disease-specific measures, utility measures, and more recently, direct questioning of objective measures[1]. The Fecal Incontinence Quality Of Life (FIQL) questionnaire, a disease-specific tool, was designed to

evaluate the impact of FI on four aspects of patients' QOL: lifestyle; coping behavior; depression or self perception; and level of embarrassment. Each aspect is described as a score measured on a scale between 1 and 4, where 1 is very affected and 4 is not affected[22]. Validity and reliability of the FIQL have been established and it has been recommended as a useful tool to assess FI[23].

This study was designed to explore the impact of FI on the QOL of patients attending urogynecology and colorectal surgical outpatient clinics at a publicly funded regional hospital with a large rural catchment[24].

MATERIALS AND METHODS

Participants

Participants were **c**onsecutive patients attending the colorectal clinic (CC) and urogynecology clinic (UC) at The Townsville Hospital, in North Queensland Australia, between January and June 2003 and August and November 2004. Ethical approval was obtained from the ethics committees of Townsville Hospital and James Cook University.

Study procedure

The study procedure has been described previously[5,9]. Briefly, a cross-sectional survey was conducted among patients at the CC and UC. On arrival, all patients attending these clinics were invited to participate in the study. Exclusion criteria included children (under 18 years), pregnancy, terminal illness, mental illness, or gastrointestinal stoma. Eligible subjects completed a patient consent form. Participants were then given a self-administered questionnaire that contained questions about patient demographics, alcohol consumption, preexisting medical conditions, and prior surgical history; all known risk factors for FI. Patients who answered "yes" to the question "do you ever accidentally soil your clothes or underclothes with feces?" proceeded to questions relating to the frequency, severity and management of FI, and the 29 question FIQL survey tool[22]. The physicians of participating patients also surveyed them using the Cleveland Clinic Florida Fecal Incontinence Score[25], which was compared with the self-administered survey tool results to investigate disclosure problems[9]. Here, we report information about the QOL questions from the self-administered questionnaire.

Statistical analysis

Mean and SD were used to describe age. Medians and interquartile ranges were used as measures of central tendency and estimates for dispersion for duration of FI and FIQL scales. FIQL scales were calculated in accordance with the developers recommendations[26]. For bivariate testing of categorical variables, exact versions of χ^2 tests were conducted for nominal items, while exact trend tests were used for ordinal variables. Multiple linear regressions were used to investigate relationships between FIQL scales and clinics, basic severity (type × frequency) and duration of FI among female participants, and FIQL scales and components of severity[2], with and without quantity of fecal loss, in all participants. Potential components were initially considered separately and were then combined. As FIQL scales were not distributed normally, they were transformed by taking the square root. As no major differences between transformed and untransformed regression results were found, the untransformed regression data have been presented. Results of linear regression analyses are presented by regression coefficients (r) with 95% CIs and/or P values. A significance level of 0.05 was adopted *a priori*.

RESULTS

The recruitment methodology and tools used were the same in 2003 and 2004. There were no differences in age (P = 0.603), sex (P = 0.149) or prevalence of FI (P = 0.076) in participants between the two recruitment periods, thus the data were combined for analysis.

Response rate

A total of 769 patients (451 in 2003 and 318 in 2004) were invited to participate. Of these, 423 women attended the UC and 146 men and 200 women attended the CC, with 93.4% (n = 718) of the eligible patients completing the self-administered FI questionnaire. As 43 patients completed the survey more than once, the initial responses were used and duplicate data were removed from the combined database, which left a total of 675 unique entries.

Prevalence

Of the 675 patients in the study 154 (22.8%; 95% CI: 19.6%-26.0%) reported having accidentally soiled their clothes or underclothes with feces and answered the FIQL questions. There were 27 men from the CC, and 127 women, 52 from the CC and 75 from the UC, with FI. The mean age (SD) of the participants with FI was 56.2 (14.3) years. There was no age difference between sexes (P = 0.281) or clinics (P = 0.82), or the women attending the two clinics (P = 0.87).

Etiology

Patients reported the following etiological risk factors for FI. There were 27 participants who reported having bowel disease (25 from CC, nine male), with 14 of them (all from CC, two male) having been diagnosed with colorectal cancer. Twenty seven women (eight from CC) had undergone vaginal repair surgery, whilst 51 women (16 from CC) reported difficult vaginal births using forceps, vacuum extraction or long second-stage labor. Twenty-one participants (11 from CC, two male) reported rectal prolapse; 23 (20 from CC, nine male) had undergone surgery for hemorrhoids, anal fissures or fistulas; 101 (39 from CC, 10 male) had urinary incontinence; 11 (six from CC, four male) had anal injuries; 18 (10 from CC, four male) had diabetes; six (four from CC, two male) reported spinal cord disease; three (one from CC, one male) had neurological disease; 39 (21

from CC, seven male) reported chronic constipation; and 17 women (five from CC) had psychiatric problems that required medication. Some patients had multiple factors.

Duration

Patients attending the UC documented having FI for a significantly longer period (median: 24 mo, IQR: 12-60), than those attending the CC [12 (6-24), $P = 0.001$). Similarly, women in the UC clinic had FI for longer than those in the CC clinic [UC = 24 (12-60); CC = 12 (6-24), $P = 0.002$].

Frequency

More than half (55.8%) of the participants admitted to soiling at least once per month: 17% (25) of patients reported soiling daily, 24% (35) weekly, 15% (22) monthly, and 44% (65) less than once a month. There was no difference in the frequency of incontinent episodes between sexes ($P = 0.678$). However, women who attended the CC reported more frequent leakage, with 27.5% soiling daily compared with 11.0% of those in the UC ($P = 0.037$), possibly as a result of their bowel condition.

Type

In the CC, significantly more men (79%) disclosed liquid bowel leakage than women (46%), whilst fewer men reported solid (8%) and combined solid/liquid (13%) leakage than women (solid = 18%, combined = 36%; $P = 0.008$). There was no significant difference between women attending the CC or UC with regard to type of leakage (UC: liquid bowel leakage, 46%; solid bowel leakage, 28%; combined solid/liquid bowel leakage, 25%, $P > 0.05$). More women attending the CC reported passive leakage (80%) than those attending the UC (62.5%, $P = 0.037$) or men (48%, $P = 0.026$). There were no differences between sexes or clinics for fecal urgency or quantity of fecal soiling.

QOL impact

The median (IQR) results of the FIQL scales (range: 1-4; 4 = not affected) for all participants were: lifestyle = 3.24 (2.22-3.80); coping = 2.23 (1.60-3.00); depression = 2.42 (1.95-3.33); and embarrassment = 2.33 (1.67-3.58) (Table 1). Participants who attended the CC had significantly poorer scores than those who attended the UC for lifestyle ($P = 0.005$), coping ($P = 0.003$) and embarrassment ($P = 0.024$) but not depression ($P = 0.056$).

There were no significant differences in any of the FIQL scales between sexes when compared in total or within the CC (Figure 1). Women who attended the CC had lower scores on all scales compared with those who attended the UC (lifestyle: $P = 0.015$; coping: $P = 0.004$; depression: $P = 0.062$; embarrassment: $P = 0.009$; Figure 1). The four multiple linear regression analyses [FIQL = clinic + duration + basic FI severity (type × frequency) + error] used to investigate the relationships between QOL of women by clinic, FI type/frequency and duration determined that the poorer QOL results in the CC with regard to clinic and type/frequency remained significant (all $P < 0.05$), whilst duration of soiling remained significant for the lifestyle, depression and embarrassment scales (all $P < 0.05$) but not for the coping scale ($P = 0.103$, Table 2).

Table 1 FIQL of patients attending CCs and UCs in North Queensland

Scale[3]	*n*[1]	Missing	Mean (range)[2]	SD	Median (IQR)
Scale 1: lifestyle	119	35	2.99 (1.0-4.0)	0.899	3.24 (2.22-3.80)
Scale 2: coping	130	24	2.36 (1.0-4.0)	0.884	2.23 (1.60-3.00)
Scale 3: depression	128	26	2.57 (1.0-4.0)	0.806	2.42 (1.95-3.33)
Scale 4: embarrassment	124	30	2.53 (1.0-4.0)	0.990	2.33 (1.67-3.58)

FIQL, Rockwood *et al*[22]; [1]Patients who consented to participate in the 2003 and 2004 studies and answered yes to ever soiling with feces, $n = 154$; [2]QOL scale of 1 represents very low functional status and 4 is not affected by FI; [3]Scales calculated as per letter to the editor. Rockwood[26].

Increasing frequency and quantity of soiling had a significant negative effect across all four QOL scales (frequency, $P < 0.001$; quantity, $P < 0.01$). QOL was poorer in participants with greater urgency and passive soiling, whilst those participants who documented both solid and liquid bowel leakage had poorer QOL than those with either alone. Not all scales reached significance (Table 3). When comparing QOL between female participants who attended the CC and UC, the scores for frequency, quantity, type and fecal urgency were significantly poorer across all FIQL scales for female participants in the CC ($P < 0.05$). Women who reported passive FI in the CC had poorer QOL scores than those in the UC for lifestyle ($P = 0.040$), coping ($P = 0.020$), depression ($P = 0.181$), and embarrassment ($P = 0.019$).

The model (FIQL = frequency + type + urgency + pad use + error) used to investigate the relationships between the four FIQL scales and the components of severity showed that the significant components that affected QOL were frequency and fecal urgency with regard to lifestyle and coping (all $P < 0.05$); and frequency and type with regard to depression and embarrassment (all $P < 0.05$). As a result of the low rate of pad usage (36% wore pads), passive leakage (68% reported) was included in the model, and the quantity of fecal loss was also investigated. This amended model (Table 4) showed: daily, solid, and large losses of stool to be significant factors for lifestyle ($P < 0.05$); monthly and daily leakage, urgency, pad wearing and large quantities of fecal loss to be significant factors for coping ($P < 0.05$); frequent and major leakage of both solid and liquid stool were significant factors for depression ($P < 0.05$); whilst frequent, solid and liquid, and passive stool loss significantly affected embarrassment ($P < 0.05$).

DISCUSSION

The major findings of this study were that more than 22% of patients who attended the UC and CC in 2003 and 2004 for matters other than FI had their QOL severely affected by FI, with the QOL of participants who

Table 2 Multiple linear regression identifying relationship between FIQL scales and clinic, duration, FI severity[1] in females [regression coefficient (95% CI)]

	Lifestyle	*P*	Coping	*P*	Depression	*P*	Embarrassment	*P*
CC	-0.582 (-0.938, -0.225)	0.002	-0.499 (-0.835, -0.162)	0.004	-0.365 (-0.685, -0.045)	0.026	-0.568 (-0.923, -0.214)	0.002
Duration (mo)	-0.002 (-0.004, 0.000)	0.042	-0.002 (-0.004, 0.000)	0.103	-0.002 (-0.004, 0.000)	0.041	-0.003 (-0.005, 0.000)	0.020
Severity (1-8)[1]	-0.159 (-0.241, -0.076)	< 0.001	-0.176 (-0.255, -0.097)	< 0.001	-0.143 (-0.216, -0.069)	< 0.001	-0.207 (-0.290, -0.124)	< 0.001

[1]Fecal incontinence (FI) severity = soiling type × frequency, i.e. liquid (1), solid (1), both (2) × daily (4), weekly (3), monthly (2), less often (1). CC: Colorectal clinic.

Table 3 Association of descriptive FI with FIQL of patients attending CCs and UCs in North Queensland

Categorical variables	Scale 1: lifestyle[1]			Scale 2: coping[1]			Scale 3: depression[1]			Scale 4: embarrassment[1]		
	n (missing)	Median (IQR)[2]	*P* value	*n* (missing)	Median (IQR)[2]	*P* value	*n* (missing)	Median (IQR)[2]	*P* value	*n* (missing)	Median (IQR)[2]	*P* value
Frequency of fecal soiling (seven cases not stated)												
Daily	24 (1)	2.10 (1.33-2.91)	< 0.001[a]	24 (1)	1.33 (1.18-1.83)	< 0.001[a]	23 (2)	1.71 (1.37-2.29)	< 0.001[a]	23 (2)	1.46 (1.00-2.07)	< 0.001[a]
Weekly	31 (4)	3.10 (2.40-3.60)		32 (3)	2.26 (1.47-2.82)		30 (5)	2.54 (2.06-3.08)		30 (5)	2.33 (1.33-3.00)	
Monthly	18 (4)	3.30 (2.60-3.70)		18 (4)	2.14 (1.94-2.82)		19 (3)	2.29 (1.77-3.38)		19 (3)	2.33 (2.00-3.33)	
Less often	48 (17)	3.70 (2.85-4.00)		54 (11)	2.88 (2.15-3.57)		52 (13)	3.02 (2.19-3.66)		50 (15)	3.00 (2.33-4.00)	
Type of fecal soiling (eight cases not stated)												
Liquid	59 (16)	3.26 (2.50-3.80)	0.077[a]	64 (11)	2.44 (1.78-3.11)	0.024[a]	62 (13)	2.78 (2.14-3.57)	0.005[a]	62 (13)	2.67 (2.00-3.67)	0.003[a]
Solid	24 (7)	3.37 (2.60-3.93)		27 (4)	2.33 (1.63-3.22)		27 (4)	2.64 (2.09-3.50)		25 (6)	2.33 (1.83-3.67)	
Both	35 (5)	3.00 (1.50-3.70)		38 (2)	2.00 (1.26-2.50)		37 (3)	2.19 (1.60-2.57)		36 (4)	2.00 (1.33-2.67)	
Quantity of fecal soiling (four cases not stated)												
Minimal soiling	65 (18)	3.60 (3.00-4.00)	< 0.001[a]	71 (12)	2.67 (2.17-3.40)	< 0.001[a]	69 (14)	2.80 (2.20-3.61)	0.001[a]	69 (14)	2.67 (2.00-3.67)	0.010[a]
Major soiling	41 (11)	3.00 (2.06-3.55)		46 (6)	2.06 (1.44-2.58)		45 (7)	2.27 (1.89-2.92)		43 (9)	2.32 (2.00-3.00)	
Soiling outer clothes	8 (1)	2.12 (1.63-2.45)		8 (1)	1.28 (1.14-1.46)		8 (1)	2.00 (1.72-2.59)		7 (2)	1.67 (1.33-2.33)	
Soiling furniture	5 (1)	1.30 (1.25-1.95)		5 (1)	1.00 (1.00-2.14)		5 (1)	1.37 (1.19-2.28)		5 (1)	1.00 (1.00-2.67)	
Fecal urgency (four cases not stated)												
Never	15 (10)	4.00 (3.30-4.00)	0.001[a]	16 (9)	3.40 (2.24-3.76)	< 0.001[a]	20 (5)	2.45 (2.19-3.40)	0.177[a]	17 (8)	2.67 (1.56-3.83)	0.507[a]
Sometimes	88 (21)	3.25 (2.22-3.70)		98 (11)	2.24 (1.60-2.96)		92 (17)	2.48 (1.88-3.37)		91 (18)	2.33 (2.00-3.33)	
Always	15 (1)	2.30 (1.80-2.60)		15 (1)	1.50 (1.33-2.06)		15 (1)	2.24 (1.77-2.64)		15 (1)	2.00 (1.33-3.33)	
Women only UC-ever	47 (11)	3.30 (2.70-3.80)	0.005[b]	52 (6)	2.44 (1.79-3.11)	0.002[b]	50 (8)	2.72 (2.08-3.56)	0.034[b]	49 (9)	2.67 (2.00-3.67)	0.003[b]
Women only CC-ever	38 (7)	2.45 (1.72-3.60)		42 (3)	1.86 (1.28-2.44)		39 (6)	2.24 (1.65-2.86)		39 (6)	2.00 (1.33-2.67)	
Passive fecal soiling (seven cases not stated)												
Never	38 (12)	3.40 (2.67-4.00)	0.086[a]	41 (9)	2.56 (1.97-3.42)	0.049[a]	43 (7)	3.05 (2.28-3.66)	0.008[a]	40 (10)	3.33 (2.33-4.00)	< 0.001[a]
Sometimes	63 (16)	3.10 (2.20-3.60)		69 (10)	2.17 (1.56-2.78)		65 (14)	2.23 (1.80-2.90)		64 (15)	2.00 (1.42-2.92)	
Always	15 (3)	2.50 (1.70-3.90)		17 (1)	2.06 (1.39-3.20)		17 (1)	2.27 (1.90-3.39)		17 (1)	2.00 (1.00-2.96)	
Women only UC-ever	36 (9)	3.30 (2.76-3.82)	0.040[b]	39 (6)	2.44 (1.78-3.22)	0.020[b]	39 (6)	2.48 (1.94-3.27)	0.181[b]	38 (7)	2.33 (1.92-3.00)	0.019[b]
Women only CC-ever	33 (7)	2.50 (1.61-3.60)		37 (3)	1.91 (1.28-2.44)		34 (6)	2.20 (1.70-2.86)		34 (6)	1.83 (1.33-2.67)	

FIQL, Rockwood *et al*[22]; *n*: Number of participants in each category. [1]Scales calculated as per letter to the editor. Rockwood[26]; [2]QOL score of 1 represents very low functional status and 4 is not affected by FI. [a]Kruskal-Wallis test; [b]Mann-Whitney *U* test.

attended the CC being poorer than that of those from the UC. Furthermore, the negative impact on participants' lives worsened with the loss of both solid and liquid stool and the increased frequency and quantity of soiling.

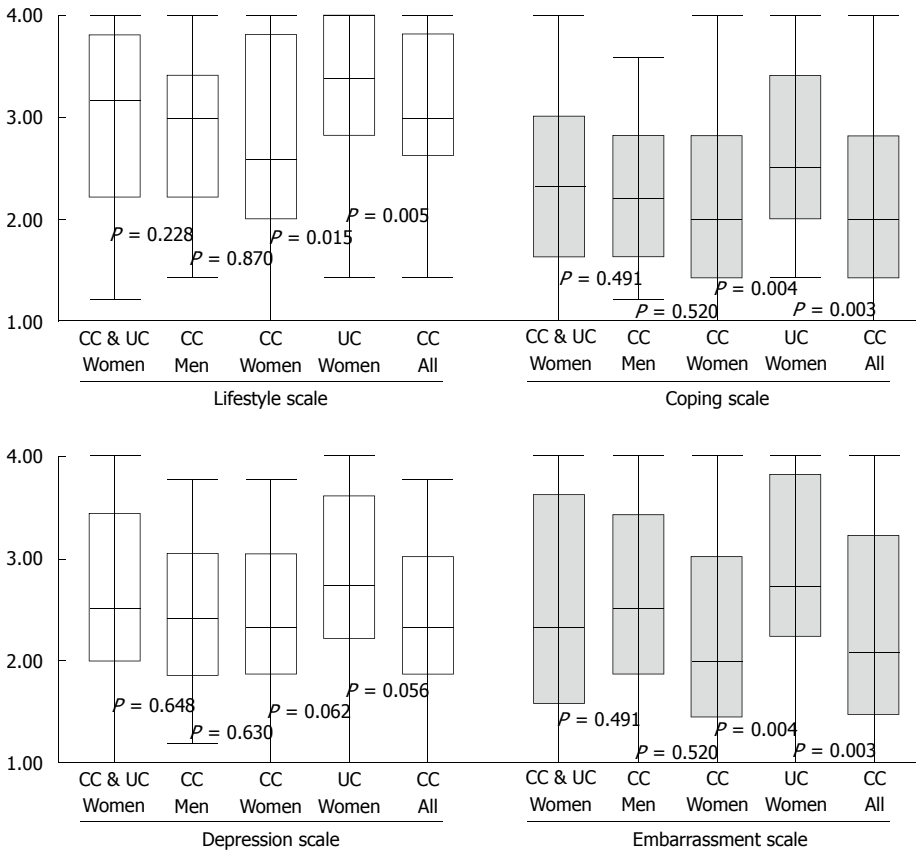

Figure 1 Association of FIQL scales with sex and CC and UC. FIQL, Rockwood *et al*[22]; Box and whisker demonstrates median, IQR, minimum and maximum. *P* values calculated by unpaired Wilcoxin test (Mann-Whitney); QOL score of 1 represents very low functional status and 4 is not affected by FI; FIQL scales calculated as per letter to the editor, Rockwood[26].

Table 4 Multiple linear regression identifying relationship between FIQL and components of FI severity

Components of FI severity	FIQL scales			
	Lifestyle	Coping	Depression	Embarrassment
Frequency				
Monthly	0.061	0.002	0.008	0.006
Weekly	0.241	0.846	0.531	0.595
Daily	< 0.001	0.012	0.023	0.021
Type				
Solid	0.010	0.192	0.515	0.633
Both solid/liquid	0.254	0.085	0.007	0.014
Urgency				
Sometimes	0.961	0.325	0.565	0.888
Always	0.106	0.023	0.554	0.636
Wears pads	0.209	0.022	0.488	0.107
Passive leakage				
Sometimes	0.659	0.169	0.103	0.787
Always	0.626	0.485	0.252	0.007
Quantity of leakage				
Major (Requires immediate underwear change)	0.001	< 0.001	0.004	0.096
Soiling of outer clothes	0.023	0.217	0.969	0.405
Soiling of furniture/bedding	0.578	0.781	0.381	0.662

In this study of the impact on QOL of FI in rural and regional north Queensland, our overall FIQL results for lifestyle (3.24), coping (2.23), depression (2.42) and embarrassment (2.33) were within the range of comparable clinic-based studies in other countries[21,27-31], and closely reflected the scores found in a similar study conducted at a Pelvic Floor Center in Minnesota, USA[21] and baseline scores from two Victorian (Australia) clinical studies that investigated injectable material for FI[32,33].

The QOL of patients who attended the CC was more severely affected than that of participants from the UC, even though they had reported FI for a shorter duration. There were no significant differences between those who had a diagnosis of bowel disease and those who did not. Thus the poorer QOL in CC participants may be a direct result of recent colorectal surgery, in which the sudden and unexpected onslaught of FI was more devastating than for the UC participants who may have learnt to cope with their progressive FI over an extended time period. These CC FIQL results are comparable with previously published results from a pouch, non-pouch study[29], but the participants in our study were less able to cope, and were more depressed and embarrassed, although this did not affect their lifestyle to the same degree.

The UC patients' QOL scores were lower than those in a similar study in Texas, USA[30] but higher than in the study in Minnesota, USA[21], for lifestyle, coping and embarrassment, but not depression. This difference may have been caused by a longer duration with FI in the older cohorts in our study and the Minnesota study, (mean age 56 years), compared with the younger cohort in the Texas study (mean age 39 years). This suggests that older women with FI had poorer QOL than younger affected women, which implies that delaying treatment for this condition results in poorer QOL over time.

This study investigated the relationship between FI severity and the FIQL scales individually and collectively. A negative impact was found on patients' lives, which increased with frequency of soiling. This was evident on all scales of the FIQL, but there was little difference in each of the FIQL scales between weekly and monthly incontinent episodes. This lack of difference may be because an incontinent episode that occurs infrequently is unexpected, and hence, would be similarly distressing.

The data collected for pad wearing was dichotomous, which may explain why only significant results for the coping scale were obtained. If, in addition, the number of pads worn per day had been assessed, the embarrassment scale may also have reached significance.

The type of soiling affected participants' QOL differently. Patients with both solid and liquid soiling reported a poorer QOL than those with either solid or liquid only incontinent episodes. This is consistent with the Texas study in which a liquid component of anal incontinence was reported to have a greater impact upon QOL of participants than either flatal or non-liquid incontinence[30].

The association between quantity of fecal loss and FIQL scales was found to be highly significant. Patients with the most soiling, i.e. those who soiled furniture, had the lowest possible FIQL score for coping and embarrassment, and performed only marginally better on the lifestyle and depression scales. There are few reports of the relationship between quantity of fecal loss and QOL, however, a Japanese study investigating the QOL of patients following total proctocolectomy and ileal J-pouch-anal anastomosis determined that greater soiling resulted in higher levels of frustration, which is an anxiety measure calculated using a Japanese translation of Cattell's anxiety scale[34]. When quantity was included in the FIQL/severity regression model, it was found to be significant ($P < 0.05$) for the lifestyle, coping and depressions scales, but did not reach significance for the embarrassment scale ($P = 0.065$). Given this relationship between the FIQL scales and quantity of fecal soiling, it is suggested that the definition of FI severity should include quantity of fecal loss as well as frequency, type, urgency and pad wearing.

In conclusion, to the best of our knowledge, this is the first study to measure the effect of FI on QOL of people in rural and regional Australia. More than 22% of the patients attending the UC and CC in North Queensland, for matters other than FI, had their QOL severely affected by this condition. Patients reported that they had not been asked about FI by their general practitioners or hospital physicians, nor did they voluntarily disclose its presence[9]. Women who have obstetric-injury-related FI suffer in silence, and their QOL deteriorates as they age. The definition of FI severity should include quantity of fecal loss[35]. Further community-based research in Australia is warranted in regard to the impact of FI on QOL of people who suffer with this complaint.

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We thank Dr. Rane AJ for facilitating access to the patients in his UCs.

COMMENTS

Background

As many as one in seven adults suffer with fecal incontinence (FI), which can have a devastating effect on the lifestyle of people with frequent, ad hoc or large amounts of fecal seepage. These people often fail to seek treatment due to embarrassment, believing the problem is uniquely theirs, or because they are unaware of the existence of available treatments.

Research frontiers

Patients referred to urogynecology and colorectal surgical clinics, for other reasons, have a high incidence of FI. They do not seek assistance whilst attending these clinics from physicians who can recommend or refer for treatment. In this study, the authors demonstrated the impact that FI had on these patients' quality of life (QOL).

Innovations and breakthroughs

Recent reports have highlighted the impact conservative treatments, such as biofeedback, and more invasive treatments, such as injectable bulking agents, sacral nerve stimulation, artificial bowel sphincter and dynamic graciloplasty, have had on the QOL of patients with FI. This study reports that despite these improvements many people continue to suffer unaware of such advances.

Applications

By understanding more than one in five patients attending colorectal and urogynecological clinics have their QOL severely affected by FI, attending physicians can enable access to treatment by directly asking patients about this problem.

Terminology

FI is the involuntary discharge of solid or liquid stools.

Peer review

FI severity, including the quantity of stool loss, can have a severe negative impact on QOL. This is an interesting and relevant study that deals with a demanding subject.

REFERENCES

1 **Baxter NN**, Rothenberger DA, Lowry AC. Measuring fecal incontinence. *Dis Colon Rectum* 2003; **46**: 1591-1605
2 **Bharucha AE**, Locke GR 3rd, Seide BM, Zinsmeister AR. A new questionnaire for constipation and faecal incontinence. *Aliment Pharmacol Ther* 2004; **20**: 355-364
3 **Miner PB Jr**. Economic and personal impact of fecal and urinary incontinence. *Gastroenterology* 2004; **126**: S8-S13
4 **Deutekom M**, Dobben AC, Dijkgraaf MG, Terra MP, Stoker J, Bossuyt PM. Costs of outpatients with fecal incontinence. *Scand J Gastroenterol* 2005; **40**: 552-558
5 **Ho YH**, Muller R, Veitch C, Rane A, Durrheim D. Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. *Aust J Rural Health* 2005; **13**: 28-34
6 **Whitehead WE**, Borrud L, Goode PS, Meikle S, Mueller ER, Tuteja A, Weidner A, Weinstein M, Ye W. Fecal Incontinence in US Adults: Epidemiology and Risk Factors. *Gastroenterology* 2009; Epub ahead of print
7 **Lam TCF**, Kennedy ML, Chen FC, Lubowski DZ, Talley NJ. Prevalence of faecal incontinence: obstetric and constipation-related risk factors; a population-based study. *Colorectal Dis* 1999; **1**: 197-203
8 **Kalantar JS**, Howell S, Talley NJ. Prevalence of faecal incontinence and associated risk factors; an underdiagnosed problem in the Australian community? *Med J Aust* 2002; **176**: 54-57
9 **Bartlett L**, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Tech Coloproctol* 2007; **11**: 251-257

10 **Leigh RJ**, Turnberg LA. Faecal incontinence: the unvoiced symptom. *Lancet* 1982; **1**: 1349-1351
11 **Drossman DA**, Sandler RS, Broom CM, McKee DC. Urgency and fecal soiling in people with bowel dysfunction. *Dig Dis Sci* 1986; **31**: 1221-1225
12 **Enck P**, Bielefeldt K, Rathmann W, Purrmann J, Tschöpe D, Erckenbrecht JF. Epidemiology of faecal incontinence in selected patient groups. *Int J Colorectal Dis* 1991; **6**: 143-146
13 **Johanson JF**, Lafferty J. Epidemiology of fecal incontinence: the silent affliction. *Am J Gastroenterol* 1996; **91**: 33-36
14 **Edwards NI**, Jones D. The prevalence of faecal incontinence in older people living at home. *Age Ageing* 2001; **30**: 503-507
15 **Whitehead WE**. Diagnosing and managing fecal incontinence: if you don't ask, they won't tell. *Gastroenterology* 2005; **129**: 6
16 **Stevens TK**, Soffer EE, Palmer RM. Fecal incontinence in elderly patients: common, treatable, yet often undiagnosed. *Cleve Clin J Med* 2003; **70**: 441-448
17 **Rothbarth J**, Bemelman WA, Meijerink WJ, Stiggelbout AM, Zwinderman AH, Buyze-Westerweel ME, Delemarre JB. What is the impact of fecal incontinence on quality of life? *Dis Colon Rectum* 2001; **44**: 67-71
18 **Colquhoun P**, Kaiser R Jr, Efron J, Weiss EG, Nogueras JJ, Vernava AM 3rd, Wexner SD. Is the quality of life better in patients with colostomy than patients with fecal incontience? *World J Surg* 2006; **30**: 1925-1928
19 **Deutekom M**, Terra MP, Dobben AC, Dijkgraaf MG, Baeten CG, Stoker J, Bossuyt PM. Impact of faecal incontinence severity on health domains. *Colorectal Dis* 2005; **7**: 263-269
20 **Damon H**, Dumas P, Mion F. Impact of anal incontinence and chronic constipation on quality of life. *Gastroenterol Clin Biol* 2004; **28**: 16-20
21 **Bordeianou L**, Rockwood T, Baxter N, Lowry A, Mellgren A, Parker S. Does incontinence severity correlate with quality of life? Prospective analysis of 502 consecutive patients. *Colorectal Dis* 2008; **10**: 273-279
22 **Rockwood TH**, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, Wexner SD, Bliss D, Lowry AC. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum* 2000; **43**: 9-16; discussion 16-17
23 **Avery KN**, Bosch JL, Gotoh M, Naughton M, Jackson S, Radley SC, Valiquette L, Batista J, Donovan JL. Questionnaires to assess urinary and anal incontinence: review and recommendations. *J Urol* 2007; **177**: 39-49
24 **Queensland Health**. The Townsville Hospital. Available from: http://www.health.qld.gov.au/townsville/Facilities/tville_hosp.asp
25 **Jorge JM**, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum* 1993; **36**: 77-97
26 **Rockwood T**. The author replies. *Dis Colon Rectum* 2008; **51**: 1434
27 **Colquhoun PH**, Efron J, Wexner SD. Attainment of continence with J-pouch and artificial bowel sphincter for concomitant imperforate anus and familial adenomatous polyposis: report of a case. *Dis Colon Rectum* 2004; **47**: 538-541
28 **Rullier E**, Zerbib F, Marrel A, Amouretti M, Lehur PA. Validation of the French version of the Fecal Incontinence Quality-of-Life (FIQL) scale. *Gastroenterol Clin Biol* 2004; **28**: 562-568
29 **Park JG**, Lee MR, Lim SB, Hong CW, Yoon SN, Kang SB, Heo SC, Jeong SY, Park KJ. Colonic J-pouch anal anastomosis after ultralow anterior resection with upper sphincter excision for low-lying rectal cancer. *World J Gastroenterol* 2005; **11**: 2570-2573
30 **Boreham MK**, Richter HE, Kenton KS, Nager CW, Gregory WT, Aronson MP, Vogt VY, McIntire DD, Schaffer JI. Anal incontinence in women presenting for gynecologic care: prevalence, risk factors, and impact upon quality of life. *Am J Obstet Gynecol* 2005; **192**: 1637-1642
31 **Pla-Martí V**, Moro-Valdezate D, Alos-Company R, Solana-Bueno A, Roig-Vila JV. The effect of surgery on quality of life in patients with faecal incontinence of obstetric origin. *Colorectal Dis* 2007; **9**: 90-95
32 **Tjandra JJ**, Lim JF, Hiscock R, Rajendra P. Injectable silicone biomaterial for fecal incontinence caused by internal anal sphincter dysfunction is effective. *Dis Colon Rectum* 2004; **47**: 2138-2146
33 **Tjandra JJ**, Chan MK, Yeh HC. Injectable silicone biomaterial (PTQ) is more effective than carbon-coated beads (Durasphere) in treating passive faecal incontinence--a randomized trial. *Colorectal Dis* 2009; **11**: 382-389
34 **Fujita S**, Kusunoki M, Shoji Y, Owada T, Utsunomiya J. Quality of life after total proctocolectomy and ileal J-pouch-anal anastomosis. *Dis Colon Rectum* 1992; **35**: 1030-1039
35 **Landefeld CS**, Bowers BJ, Feld AD, Hartmann KE, Hoffman E, Ingber MJ, King JT Jr, McDougal WS, Nelson H, Orav EJ, Pignone M, Richardson LH, Rohrbaugh RM, Siebens HC, Trock BJ. National Institutes of Health state-of-the-science conference statement: prevention of fecal and urinary incontinence in adults. *Ann Intern Med* 2008; **148**: 449-458

S- Editor Tian L **L- Editor** Kerr C **E- Editor** Zheng XM

4.2 Additional (unpublished) findings

Further analyses relevant to this chapter include a comparison of the effect of untreated faecal incontinence on quality of life over time and between the different clinical studies conducted during this work.

To compare the impact of faecal incontinence on quality of life of participants in the disclosure studies (Chapter 4.1) and the biofeedback studies (Chapter 5.1 and 5.4) the initial continence score and quality of life scales are reported in Table 4.1. The data of 15 patients who participated in both disclosure and biofeedback studies were not duplicated; their initial biofeedback study scores are reported. For those participants (15, 11 Colorectal: 2 x 2003, and 4 urogynaecological: 2 x 2003) continence was significantly worse (P=0.03) by the time they enrolled in biofeedback treatment 15.4 months later (IQR:10-24). However their quality of life had improved, although only significantly for the depression scale (P=0.05). This improvement may have been due to anticipating professional treatment.

Across the four studies, women with faecal incontinence found the condition significantly more embarrassing than men although their severity, coping, depression and lifestyle scores were similar. With the exception of the lifestyle component, the effect of faecal incontinence on the quality of life of participants attending biofeedback treatment was significantly poorer than those attending the urogynaecology and colorectal outpatient clinic. The severity of their faecal incontinence was also significantly worse (Table 4.1).

These studies highlight the importance of seeking early treatment for faecal incontinence.

Table 4.1: Severity and quality of life burden of all research participants

Initial survey	n	Continence Score[1]	Fecal Incontinence Quality of Life Scale[2]			
			Lifestyle	Coping	Depression	Embarrassment
Disclosure study 1 (, Chapter 4.1)	85	3.0 (0-7)	3.3	2.4	2.7	2.7
Disclosure study 2 (Chapters 2.1, 4.1)	56	6.0 (2-12)	3.0	2.1	2.3	2.3
Biofeedback exercise study (Chapter 5.1)	72	11.5 (8-15)	3.4	2.3	2.8	2.2
Home biofeedback study (Chapter 5.4)	75	14.0 (10-16)	3.3	1.9	3.0	2.0
Male	55	8.0 (3-13)	3.2	2.3	2.8	2.7
Female	233	10.0 (3-14)	3.3	2.1	2.7	2.0
P		(0.237)	(0.528)	(0.565)	(0.280)	**(0.039)**
Disclosure	141	8.0 (3-13)	3.2	2.3	2.8	2.7
Biofeedback	147	10.0 (3-14)	3.3	2.1	2.7	2.0
P		**(<0.001)**	(0.588)	**(0.040)**	**(0.019)**	**(0.006)**

[1] Median (IQR) Cleveland Clinic Florida Fecal Incontinence Score (Jorge & Wexner 1993): 0 = continent, 20 =At least once daily: solid + liquid stool +flatus leakage, wears pads and quality of life burdened

[2] Median Fecal Incontinence Quality of Life Scale (Rockwood 2000): 1 = very affected by faecal incontinence, 4 = not affected by faecal incontinence

CHAPTER 5: BIOFEEDBACK THERAPY

Anorectal biofeedback is a safe, conservative, first-line therapy for patients with mild to moderate faecal incontinence who have not responded to general practitioner prescribed dietary advice, pelvic floor exercises or medication after 6 – 12 months. Anorectal biofeedback has no known side effects. An inflated balloon is positioned in the rectal vault and a catheter with a pressure transducer placed in the patient's anal canal to measure pelvic floor muscle activity and convert anal pressure readings to a display screen for immediate visual feedback. The aim of anorectal biofeedback is to enable patients to identify, contract, and relax the pelvic floor muscles, including the anal sphincter.

Effective pelvic floor muscles, including the external anal sphincter, support the abdominal contents against gravity and help maintain urinary and faecal continence. Pelvic floor muscle training increases the strength and endurance of the muscles, stimulates the pudendal nerve, and improves blood flow to the rectum or reservoir, anal region and pelvic floor, thereby reducing incontinent episodes due to abdominal pressure following exertion. Muscle building principles dictate that the quality of contractions/squeezes is more important than the quantity [1].

The Anorectal Physiology Clinic at the Townsville Hospital, Queensland, Australia (a publicly funded regional hospital with a large rural catchment), has offered a biofeedback treatment program for faecal incontinence, chronic constipation, post-surgery bowel dysfunction, incomplete stool evacuation or stool fragmentation and pelvic pain or muscle spasm since 2002. The program combines behavioural strategies and biofeedback therapy in a series of weekly one-on-one sessions with a biofeedback therapist. After 3 - 4 sessions a break of four weeks enables home practice of skills learnt before patients return for a final follow-up session.

The section of the work investigates the biofeedback program offered at the Townsville Hospital for those with faecal incontinence. The first randomised clinical trial focussed on the exercises prescribed as a Cochrane review suggested the need for studies investigating biofeedback therapy and sphincter exercises [2]. Additional analyses assessed whether therapy outcomes differed depending on participant location (distance from clinic) or, whether biofeedback therapy was helpful for faecal incontinence caused by surgery for colorectal cancer.

Participants in the first randomised clinical trial reported they were not confident they could perform the exercises correctly at home. This prompted the design of a second biofeedback study which included the use of supplementary portable perineometers. While it had been reported that home biofeedback did not improve faecal incontinence over standard advice; or standard advice and exercises, or standard advice, exercises and biofeedback [3], 90 per cent of participants from our first biofeedback study were quite willing to try them.

Study aims:

- *To investigate the effect of sustained pelvic floor and anal sphincter squeezes with and without rapid squeezes on continence and quality of life in patients attending the anorectal clinic for faecal incontinence*
- *To determine if the effect of anorectal biofeedback therapy on faecally incontinent patient outcomes was different depending on the distance from the clinic*
- *To investigate the effect of the anorectal biofeedback therapy on continence and quality of life in patients with faecal incontinence caused by surgery for colorectal cancer*
- *To report the methodology of the Townsville Hospital biofeedback therapy program for patients with faecal incontinence caused by surgery for colorectal cancer:*
  - *Practical coping strategies*
  - *Clinical anorectal biofeedback*
- *To investigate the effect of supplementary home biofeedback on the continence and quality of life in patients attending the anorectal clinic for faecal incontinence*

Publications arising from this chapter

5.1 Evaluation of pelvic floor and anal sphincter exercises

Bartlett L, Sloots K, N owak M, Ho Y-H. Biofeedback for fae cal incontinence: a randomized control study comparing exercise regimen. *Diseases of the Colon and Rectum*. 2011;54:846-856.

My estimated contribution was 76% (Contributors table, page xv)

5.2 Impact of biofeedback therapy on rural and regional patients

Bartlett L, Sloots K, Nowak M, Ho YH. Biofeedback therapy for faecal incontinence: a rural and regional perspective. *Rural and Remote Health*. 2011;11:1630

My estimated contribution was 85% (Contributors table, page xv)

5.3 Impact of biofeedback therapy in patients who had faecal incontinence following bowel surgery as a treatment for colorectal cancer

Bartlett L, Sloots K, Nowak M, Ho YH. Biofeedback therapy for symptoms of bowel dysfunction following surgery for colorectal cancer. *Techniques in Coloproctology*. 2011;15:319-326:

My estimated contribution was 84% (Contributors table, page xv)

5.4 Practical Strategies for treating patients who had faecal incontinence following bowel surgery as a treatment for colorectal cancer

Sloots K, Bartlett L. Practical strategies for treating postsurgical bowel dysfunction. *Journal of Wound, Oostomy, and Continence Nursing*. 2009;36:522-7

My estimated contribution was 10% (Contributors table, page xv)

5.5 Biofeedback therapy methodology for treating patients who had faecal incontinence following bowel surgery as a treatment for colorectal cancer

Sloots K, Bartlett L, Ho YH. Treatment of postsurgery bowel dysfunction: biofeedback therapy. *Journal of Wound, Ostomy, and Continence Nursing*. 2009;36:651-8

My estimated contribution was 10% (Contributors table, page xv)

5.6 Supplementary home biofeedback

Bartlett L, Sloots K, Nowak M, Ho. Y. S upplementary home biofeedback improves quality of life in younger patients with fecal incontinence. *Journal of Clinical Gastroenterology*, 2013 ***(In press)***

My estimated contribution was 86% (Contributors table, page xv)

References

1. DiNubile NA, Strength training. *Clinics in Sports Medicine*, 1991. 10(1): 33-62.
2. Norton C, Cody JD, Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *The Cochrane Database of Systematic Reviews*, 2012. 7: CD002111.
3. Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA, Randomized controlled trial of biofeedback for fecal incontinence. *Gastroenterology*, 2003. 125(5): 1320-9.

ORIGINAL CONTRIBUTION

Biofeedback for Fecal Incontinence: A Randomized Study Comparing Exercise Regimens

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BACKGROUND: Fecal incontinence affects up to 11% of Australian community-dwelling adults and 72% of nursing home residents. Biofeedback is a recommended conservative therapy when medication and pelvic floor exercises have failed to improve patient outcomes.

OBJECTIVE: This study aimed to investigate the impact of a new exercise regimen on the severity of fecal incontinence and the quality of life of participants.

DESIGN: This was a randomized clinical study.

SETTINGS: This study was conducted at the Anorectal Physiology Clinic, Townsville Hospital, Queensland, Australia.

PATIENTS: Seventy-two participants (19 male), with a mean age of 62.1 years, attended 5 clinic sessions: 4 weekly sessions followed by 4 weeks of home practice and a follow-up assessment session. A postal survey was conducted 2 years later.

INTERVENTION: Thirty-seven patients (12 male) were randomly assigned to the standard clinical protocol (sustained submaximal anal and pelvic floor exercises) and 35 patients (7 male) were randomly assigned to the alternative group (rapid squeeze plus sustained submaximal exercises).

MAIN OUTCOME MEASURES: The main outcomes were measured by use of the Cleveland Clinic Florida Fecal Incontinence score and the Fecal Incontinence Quality of Life Scale survey tool.

RESULTS: No significant differences were found between the 2 exercise groups at the beginning or at the end of the study or as a result of treatment in objective, quality-of-life, or fecal incontinence severity measures. Sixty-nine participants completed treatment. The severity of fecal incontinence decreased significantly (11.5/20 to 5.0/20, $P < .001$). Eighty-six percent (59/69) of participants reported improved continence. Quality of life significantly improved for all participants ($P < .001$). Results were sustained 2 years later. Patients who practiced at least the prescribed number of exercises had better outcomes than those who practiced fewer exercises.

LIMITATIONS: This study was limited because it involved a heterogeneous sample, it was based on subjective reporting of exercise performance, and loss to follow-up occurred because of the highly mobile population.

CONCLUSIONS: Patients attending this biofeedback program attained significant improvement in the severity of their fecal incontinence and in their quality of life. Although introduction of rapid muscle squeezes had little impact on fecal incontinence severity or patient quality of life, patient exercise compliance at prescribed or greater levels did.

KEY WORDS: Biofeedback; Fecal incontinence; Quality of life; Pelvic floor exercises; Exercise compliance; Randomized clinical study.

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Fecal incontinence (FI), the involuntary loss of liquid or solid stool with or without the patient's awareness, may negatively affect quality of life (QOL) resulting in embarrassment, loss of confidence and self-respect, psychiatric disorders, social isolation, and lost economic productivity.[1] Australian studies estimate the community prevalence of FI to be between 8% and 11%.[2–4] North Queensland clinical studies found more than 20% of colorectal and urogynecological outpatients had FI.[1,5] Up to 72% of Australian nursing home residents have FI.[6]

One safe, conservative first-line treatment is biofeedback-assisted exercise.[7] The Townsville Hospital, a publicly funded regional hospital with a large rural catchment, operates a holistic biofeedback clinic for FI, constipation, and chronic pelvic pain.[8,9]

Pelvic floor muscles support the abdominal contents helping maintain urinary and fecal continence. Pelvic floor muscle training increases the strength and endurance of the muscles, stimulates the nerves supplying the muscles, improves blood flow to the rectum or reservoir, anal region, and pelvic floor, and increases anatomical awareness to assist in reducing incontinent episodes. Muscle-building principles imply that the quality of contractions/squeezes is more important than the quantity.[10] Sustained (submaximal) anal sphincter and pelvic floor muscle exercises were routinely included in the Townsville Hospital biofeedback program to improve bowel continence, decrease urgency, moderate rectal or pouch sensitivity, encourage effective evacuation, and increase patient confidence.

A Cochrane review suggested the need for randomized clinical trials comparing exercises.[11] A standard exercise program incorporating rapid squeezes (to improve muscle bulk and reaction time[12]) and sustained contractions (to improve strength and endurance) was recommended.[13] This randomized clinical study was designed to compare a regimen of sustained plus rapid exercises with the standard exercise regimen of sustained exercises and those elements which could provide insight into the success of biofeedback therapy.

METHODS

Participants

More than 250 patients with FI were referred to a Townsville colorectal surgeon between 2004 and 2008; treatments included anal implants, medication, surgery, and biofeedback.[14] Of those referred for biofeedback before October 2006, 101 were assessed for eligibility for this study. Twenty-nine were excluded: 26 had relocated without a forwarding address, 2 did not meet selection criteria, and one refused to participate (Fig. 1). After anorectal manometric assessment and endoanal ultrasound, 72 eligible participants (19 male), with a mean age of 62.1 years (range, 32–82), consented to participate between January 2005 and October 2006 (Table 1). Females were younger than males (mean age/range = 60.5/32–82 vs 66.7/51–81; $P = .052$). They were at least 18 years old, were not pregnant, and had no terminal illness, mental illness, or gastrointestinal stoma. No participant had sacral nerve stimulation before or during this study. Their FI had failed to respond to conservative treatment prescribed by their general practitioner over a 6- to 12-month period.

Randomization

A total of 37 patients were randomly assigned to the standard clinical protocol of sustained submaximal anal sphincter and pelvic floor muscle exercises (SE group), and 35 were randomly assigned (in parallel) to the alternative group of rapid squeeze exercises and standard submaximal sustained anal sphincter and pelvic floor muscle exercises (RSE group; Fig. 1, Table 1). Independent unrestricted randomization was performed before study commencement using a computer-generated sequence. The study arm was placed in a sealed opaque envelope with the participant identification number on the front and given to the therapist immediately before session 3. Participants were blinded. Researcher (L.B.) received the randomization sequence immediately before analysis.

Ethics

The Townsville Hospital (47/04) and James Cook University (H1950) gave ethical approval. The Australian New Zealand Clinical Trials Registry number is ACTRN12610000258055.

Study Procedure

The biofeedback nurse therapist (K.S.) telephoned patients, explained the study, and invited them to participate. Treatment included 5 outpatient sessions, over 8 weeks. The first 4 sessions were weekly; participants then practiced techniques for 4 weeks before returning for their final session.

At their first attendance patients met with the researcher (L.B.), completed consent forms, a self-administered FI questionnaire,[1] the 29-question Fecal Incontinence Quality of Life Scale (FIQL) survey tool,[15,16] and the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI).[17]

Biofeedback session 1 included a review of relevant medical, surgical, obstetric, and medication history. Usual bowel habits and associated problems, diet, fiber, and fluid intake were discussed as were the aim of therapy and goal establishment. The therapist presented coping strategies and dietary advice.[8] Participants were given charts to facilitate recording daily bowel accidents and toileted movements, food intake, and medication used. Assessment of anorectal function included mean anal resting sphincter pressure, mean maximal voluntary contraction squeeze

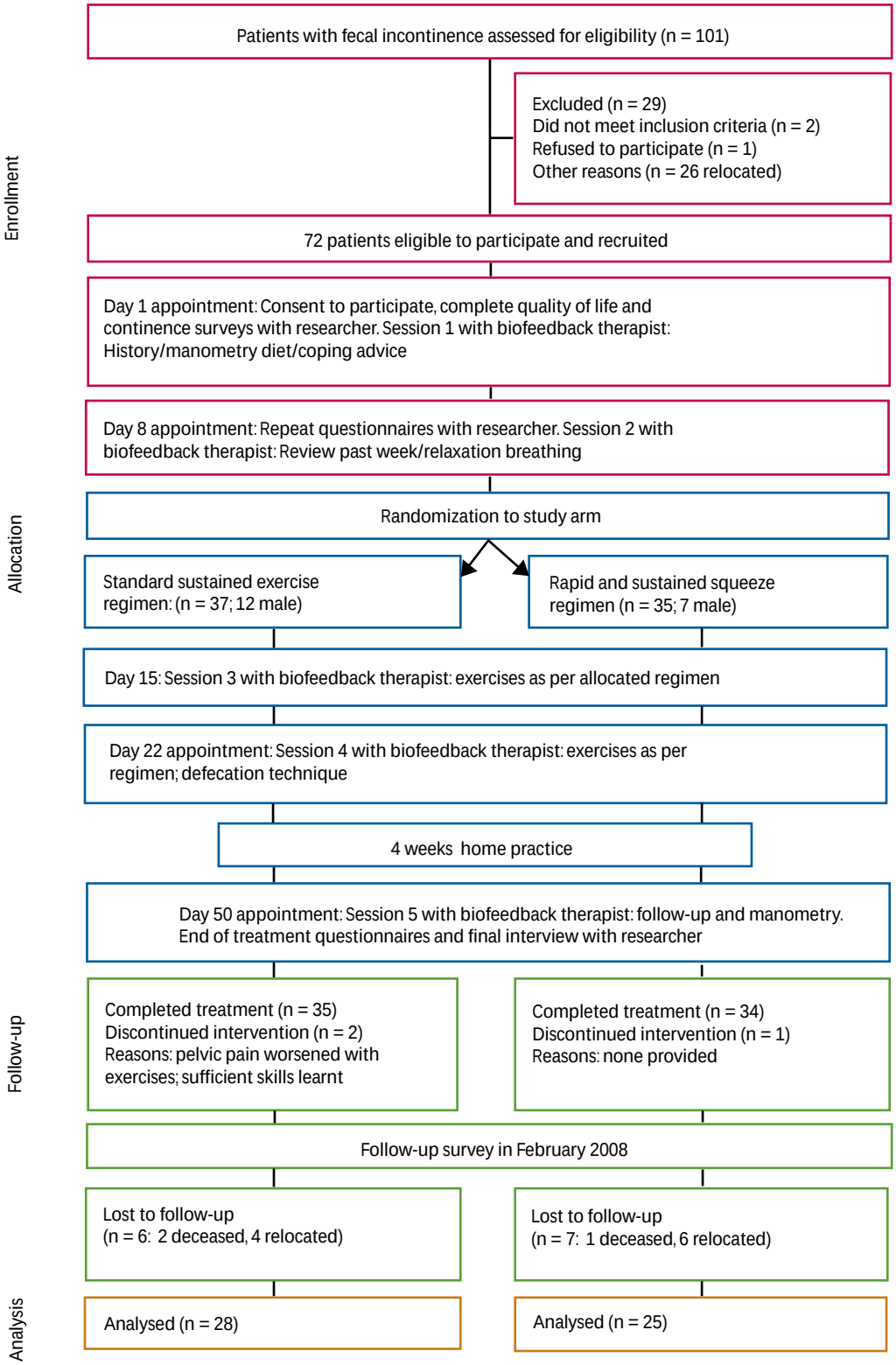

FIGURE 1. Progress of participants through study (Consort diagram).

TABLE 1. Patient demographic data

Variable	*All Participants*	*Sustained exercise group (control) (n = 37)*	*Rapid and sustained exercise group (intervention) (n = 35)*	*P*
Age, mean (range)	62.1 (32–82)	62.0 (32–82)	62.2 (38–82)	.952
Duration of fecal incontinence (months, median/IQR)	24 (18–48)	24 (16.5–42)	24 (18–60)	.417
Sex M/F	19/53	12/25	7/28	.232
Diabetes	8	5	3	.387
Rectal prolapse	9	5	4	.536
Chronic constipation	9	6	3	.268
Rectal emptying problems (male)	8 (4)	4	4	1.000
Psychiatric problems–depression	8	4	4	.613
Colon disease	23	15	8	.108
Spinal cord disease	2	1	1	.739
Neurological disease	2	2	0	.261
Urinary incontinence	26	14	12	.754
Hemorrhoidectomy	33	15	18	.354
Bowel surgery (for cancer)	20 (12)	14	6	**.050**
Injury to anus	5	2	3	.473
Radiation therapy	9	5	4	.536
Vaginal repair surgery[a]	17	8	7	.572
Difficult delivery[a]	36	17	19	.991
External anal sphincter defects (repaired)[a]	38 (13)	18	20	.866

IQR = interquartile range.
[a]Female participants only.

pressures, anal canal length, the rectosphincteric inhibitory reflex, and the volumes required to produce initial sensation, the first urge to evacuate, and maximum tolerated volume.[18,19]

In session 2 the therapist reviewed the previous week with the patient, including the completed bowel chart and the impact of any dietary changes or coping strategies. Each patient was instructed in relaxation (diaphragmatic) breathing[9] and encouraged to practice this technique for 7 to 10 minutes at least twice per day and to complete a bowel chart daily.

In session 3, following review of the previous week, participants were instructed in anal sphincter and pelvic floor muscle exercises according to their randomized exercise regimen (Fig. 2). Patients were prepared for biofeedback with an anal catheter and a rectal balloon, inflated to sensory threshold (stimulate anatomical awareness). Participants were coached to link pressure changes seen on the computer monitor with the exercises performed and sensations felt. They were instructed to use the exercises and techniques to reduce urgency and frequency, and to improve sensitivity, anorectal coordination, and continence.[9] Individualized instruction sheets were provided to enhance home performance of prescribed exercises.

Treatment components previously taught were reviewed in session 4; the exercises were adjusted and

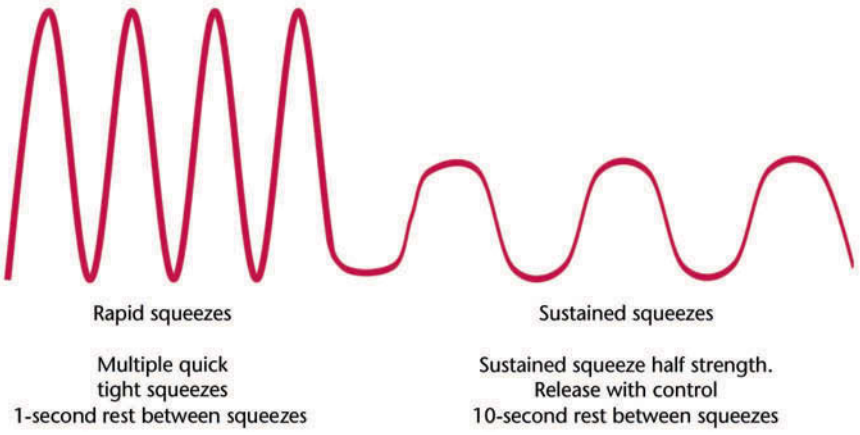

FIGURE 2. Daily exercises (anal sphincter and pelvic floor muscle).

TABLE 2. Continence, quality-of-life, and anorectal physiology changes compared by exercise regime

		Pretherapy		*Posttherapy*			*2-year follow-up*		
	Exercise regime	*Median (IQR)*	*(n)*	*Median (IQR)*	*(n)*	*P*	*Median (IQR)*	*(n)*	*P*
FIQL subscales[a]									
Lifestyle	SE	3.5 (2.4–3.9)	(37)	3.8 (3.1–4.0)	(35)	.787[b]	3.9 (3.2–4.0)	(28)	.907[c]
	RSE	3.3 (2.8–3.7)	(35)	3.7 (3.4–3.9)	(34)		3.8 (3.4–4.0)	(25)	
	All	3.4 (2.7–3.8)	(72)	3.8 (3.4–4.0)	(69)	**<.001[d]**	3.8 (3.3–4.0)	(53)	.880[e]
Coping	SE	2.1 (1.3–3.1)	(37)	2.9 (2.3–3.5)	(35)	.517[b]	3.2 (2.3–4.0)	(28)	.277[c]
	RSE	2.3 (1.6–2.7)	(35)	3.3 (2.5–3.7)	(34)		3.2 (2.7–3.8)	(25)	
	All	2.3 (1.4–2.8)	(72)	3.1 (2.4–3.6)	(69)	**<.001[d]**	3.2 (2.5–4.0)	(53)	.754[e]
Depression	SE	3.0 (2.2–3.6)	(37)	3.5 (3.0–3.8)	(35)	.843[b]	3.4 (2.8–3.9)	(28)	.063[c]
	RSE	2.7 (2.3–3.4)	(35)	3.3 (3.1–3.5)	(34)		3.6 (2.9–3.8)	(25)	
	All	2.8 (2.3–3.4)	(72)	3.4 (3.0–3.6)	(69)	**<.001[d]**	3.6 (2.9–3.8)	(53)	.845[e]
Embarrassment	SE	2.3 (1.7–3.0)	(37)	3.5 (2.7–4.0)	(35)	.762[b]	3.7 (2.2–4.0)	(28)	.229[c]
	RSE	2.0 (1.7–2.7)	(35)	3.3 (2.6–3.7)	(34)		3.7 (2.5–4.0)	(25)	
	All	2.2 (1.7–3.0)	(72)	3.3 (2.7–3.8)	(69)	**<.001[d]**	3.7 (2.5–4.0)	(53)	.281[e]
Continence grading scale[f]									
Total score (max 20)	SE	12.0 (9.0–15)	(37)	5.0 (3.0–8.0)	(35)	.312[b]	4.0 (1.0–8.0)	(27)	.825[c]
	RSE	11.0 (8.0–15)	(35)	4.5 (2.8–7.3)	(34)		4.0 (1.0–8.0)	(25)	
	All	11.5 (8.3–15)	(72)	5.0 (3.0–8.0)	(69)	**<.001[d]**	4.0 (1.0–8.0)	(52)	.820[e]
Solid + liquid FI score (max 8)	SE	4.0 (3.0–6.0)	(37)	2.0 (1.0–3.0)	(35)	.123[b]	1.0 (0.0–2.0)	(27)	.896[c]
	RSE	4.0 (3.0–6.0)	(35)	2.0 (0.8–3.0)	(34)		1.0 (0.0–3.3)	(25)	
	All	4.0 (3.0–6.0)	(72)	2.0 (1.0–3.0)	(69)	**<.001[d]**	1.0 (0.0–3.0)	(52)	.707[e]
Anorectal physiology									
Mean maximal resting pressure (mmHg)	SE	34.6 (21–50)	(37)	32.4 (19–53)	(35)	.806[b]			
	RSE	30.1 (22–49)	(35)	31.6 (23–53)	(33)				
	All	34.6 (22–49)	(72)	32.0 (21–53)	(68)	.071[d]			
Maximum squeeze pressure (mmHg)	SE	61.0 (37–99)	(37)	68.4 (51–113)	(35)	.663[b]			
	RSE	58.8 (38–90)	(35)	57.4 (43–113)	(33)				
	All	59.2 (38–90)	(72)	67.3 (46–111)	(68)	**<.001[d]**			
Volume of initial sensation (mL)	SE	28 (18–43)	(37)	20 (16–30)	(34)	.628[b]			
	RSE	25 (18–38)	(35)	21 (15–35)	(30)				
	All	28 (18–40)	(72)	20 (15–30)	(64)	**.027[d]**			
Volume at first urge (mL)	SE	75 (53–113)	(37)	75 (50–98)	(33)	.973[b]			
	RSE	70 (55–95)	(35)	60 (49–85)	(30)				
	All	73.5 (55–100)	(72)	60 (50–85)	(63)	.058[d]			
Maximum tolerable volume (mL)	SE	160 (115–200)	(37)	125 (104–173)	(34)	.454[b]			
	RSE	148 (104–163)	(35)	125 (90–161)	(30)				
	All	150 (110–180)	(72)	125 (96–165)	(64)	**.023[d]**			

n = number of patients; FI = fecal incontinence; FIQL = Fecal Incontinence Quality of Life Scale; IQR = interquartile range; SE = sustained exercise group (control); RSE = rapid and sustained exercise (intervention).
[a]FIQL, Rockwood et al[15]; scales calculated as per Rockwood 2008.[16]
[b]*P* value comparing changes pre- and posttherapy was measured using the Wilcoxon unpaired test.
[c]*P* value comparing difference between final session and 2-year follow-up was measured using the Wilcoxon unpaired test.
[d]*P* value comparing pre- and posttherapy using Wilcoxon paired signed rank test.
[e]*P* value comparing final session and 2-year follow-up was measured using Wilcoxon paired signed rank test.
[f]Cleveland Clinic Florida Fecal Incontinence Score.

practiced again with use of the computer monitor according to the individual's progress. The final treatment component involved a combination of toileting position, relaxation breathing, and evacuation technique to improve evacuation and decrease stool fragmentation.[9] Participants received updated written and verbal instructions for use during the 4 weeks of home practice.

At the final session, anorectal function, exercise regimens, bowel charts, and the 4-week home practice period were assessed with suggestions for future improvements. Patients were encouraged to continue practicing the exercises and techniques and were advised that, once satisfactory results were achieved, they could reduce the number of daily exercises to a maintenance level. An additional appointment was offered if required. Symptom severity and the effect of FI on QOL were reassessed, patient satisfaction with progress was recorded, and a short, semistructured interview was conducted.

The February 2008 follow-up survey included the CCF-FI and FIQL and questions about continued performance of prescribed exercises, type[20] and number of bowel movements per day, any postbiofeedback FI treatments and dietary or medication changes that may have affected FI.

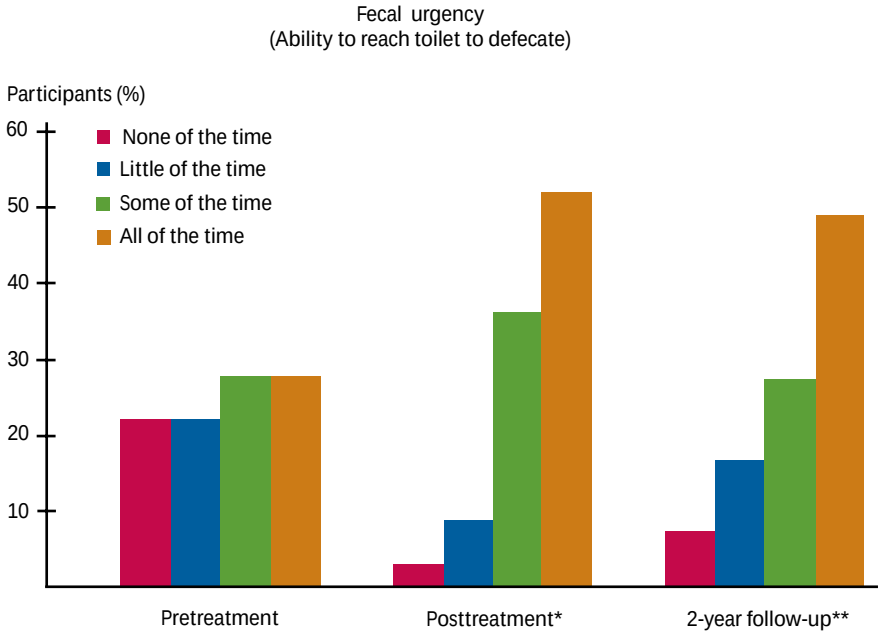

FIGURE 3. Improvement in fecal urgency, *$P < .001$, pretreatment vs posttreatment (Wilcoxon signed rank test); **$P = .336$, 2-year follow-up vs posttreatment (Wilcoxon signed rank test).

Statistical Analysis

The sample size of 34 participants per exercise group (5% α, 80% power) was calculated from data of FI patients previously treated (CCF-FI improvement, mean 2.9/SD 2.989). We hypothesized a CCF-FI improvement of 5.0 for the RSE group. Because 5% of patients had previously not completed biofeedback, we enrolled 72 participants.

Patients who did not complete the program were treated as missing. Numerical data are presented as mean and range or median and interquartile range, depending on the distribution. Comparisons between characteristics were calculated using χ^2 tests and χ^2 tests for trend, nonparametric Wilcoxon tests, and *t* tests. Exercise dose–response effects and initial FI severity were evaluated to test for trends in global FIQL and CCF-FI improvement with use of the Spearman rank correlation coefficient (r_s). Statistical analyses were conducted using SPSS for Windows version 17 (SPSS Inc, Chicago, IL). A significance level of .05 was adopted a priori.

RESULTS

Enrolled patients reported having FI for 24 (interquartile range, 18–48) months. Although more participants in the SE group had undergone bowel surgery ($P = .05$), no other significant differences in baseline demographic or clinical characteristics between the 2 groups were reported (Table 1). Sixty-nine participants (35 SE) completed all 5 treatment sessions (median duration, 8 weeks).

There were no significant differences between the 2 exercise groups at the beginning and at the end or as a result of treatment in the objective manometric measurements, FIQL subscales, or CCF-FI (Table 2). Nor were there any differences between the exercise groups in rating individual treatment components, satisfaction with results of the treatment program, or improvement in subjective bowel function. Thus, their data were pooled. There were no adverse events.

The biofeedback treatment was efficacious with substantially improved continence and QOL over the treatment period and at 2008 follow-up ($P < .001$, Friedman nonparametric repeated measurements test). Between the initial and final treatment sessions there were significant reductions in incontinent episodes (4 (range, 1–11.5) to 1 (range, 0–2.3) per week, $P < .001$) and stool frequency (13 (range, 8–28) to 12 (range, 8–20) bowel movements per week, $P = .007$) recorded in the bowel diaries. Fecal urgency improved significantly ($P < .001$; Fig. 3) and FI severity reduced significantly (Table 2; $P < .001$). At the final session, 86% (59/69) of participants had improved continence, and 20% (14/69) reported no fecal leakage in the preceding month. Patients' QOL was improved, with an increase in all 4 FIQL subscales ($P < .001$; Table 2). Improvement in QOL was correlated with the initial FI severity (CCF-FI less the lifestyle aspect, $r_s = 0.274$, $P = .023$; Fig. 4). There was significant improvement in the patients' subjective rating of bowel control over the treatment period (0 = worst, 10 = best), from 3 (range, 1.8–4) to 7.5 (range, 6.3–8.6), $P < .001$. Objective anorectal manometric and proctometrographic measurements, recorded at the first and final biofeedback sessions (Table 2) were significantly

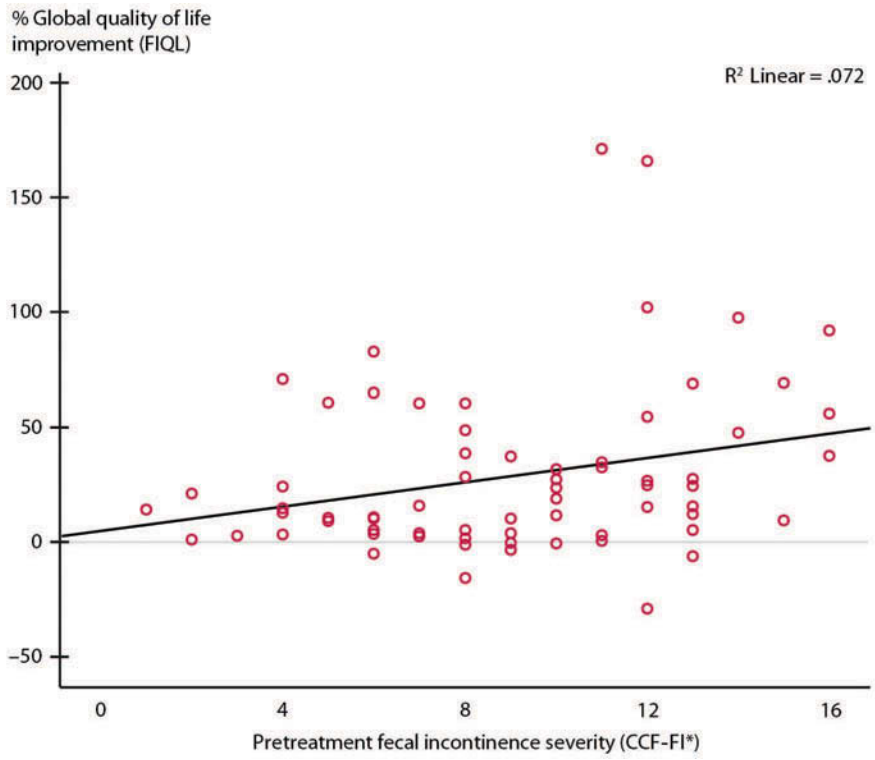

FIGURE 4. Relationship between quality-of-life improvement and initial fecal incontinence severity; n = 69, median improvement (interquartile range) 15.7% (3.8%–43.0%), $r_s = 0.274$, $P = .023$. CCF-FI = Cleveland Clinic Florida Fecal Incontinence Score; FIQL = Fecal Incontinence Quality of Life Scale. *Lifestyle component omitted.

improved for maximum squeeze pressure ($P < .001$) and volume of initial sensation ($P = .027$), marginally different for mean resting pressures and volume at first urge, and the maximum volume tolerated decreased ($P = .023$).

At 2 years, 13 participants were lost to follow-up (3 were deceased, 10 could not be contacted). FIQL and CCF-FI results continued to improve, although not significantly, among the 53 participants who provided this information (Table 2); 38% (20/53) reported no fecal leakage. Initial FI severity and QOL improvement at the 2 years follow-up was poorly correlated ($r_s = 0.116$, $P = .407$; Fig. 5).

Performance of Exercises

Prescribed squeeze-seconds per day for week 4 and the home practice period are reported in Table 3, as are those performed and the proportion of participants who complied with the exercise prescription. From the patient diaries 22 (12 SE) participants performed at least the prescribed number of exercise seconds in week 4, and the week 8 diaries showed that the SE group performed 195 (range, 94–343) seconds per day and the RSE group performed 264 (range, 54–357) seconds per day (Table 3). Participants who completed at least 100% of prescribed exercises, on average, exercised 50% more than prescribed at week 4 and 18% more at week 8. There was no significant difference for exercise prescription or compliance between the SE and RSE groups. Before treatment, compliant participants (n = 26, 12 SE/14 RSE; mean compliance, 118%) had significantly poorer continence scores ($P = .014$) and FIQL scores (lifestyle, $P = .018$; coping, $P = .004$; depression, $P = .003$; embarrassment, $P = .04$), than noncompliers (n = 34, 17 SE/17 RSE; mean compliance, 52%). Improvement in FIQL scores for compliers, over the duration of treatment, was significantly greater than for noncompliers (lifestyle, $P = .046$; coping, $P = .015$; depression, $P = .002$; embarrassment, $P = .011$), as was their reduction in incontinent episodes ($P = .045$). An improvement in QOL (global FIQL) and FI severity (CCF-FI) was directly related to exercise performance ($r_s = 0.357$, $P = .005$ and $r_s = 0.136$, $P = .301$).

At 2 years, 84.9% of participants (45) reported remembering how to perform their exercises; 21 of 30 (70%) of the SE group and 20 of 28 (71%) of the RSE group still practiced their exercises but less frequently than recommended (Table 3). Although improvement in FI increased over the 2 years, continence scores and FIQL scores were not significantly different between the participants who continued to perform their exercises and those who did not.

DISCUSSION

The major finding of this study was that there were no significant differences in objective or subjective measures

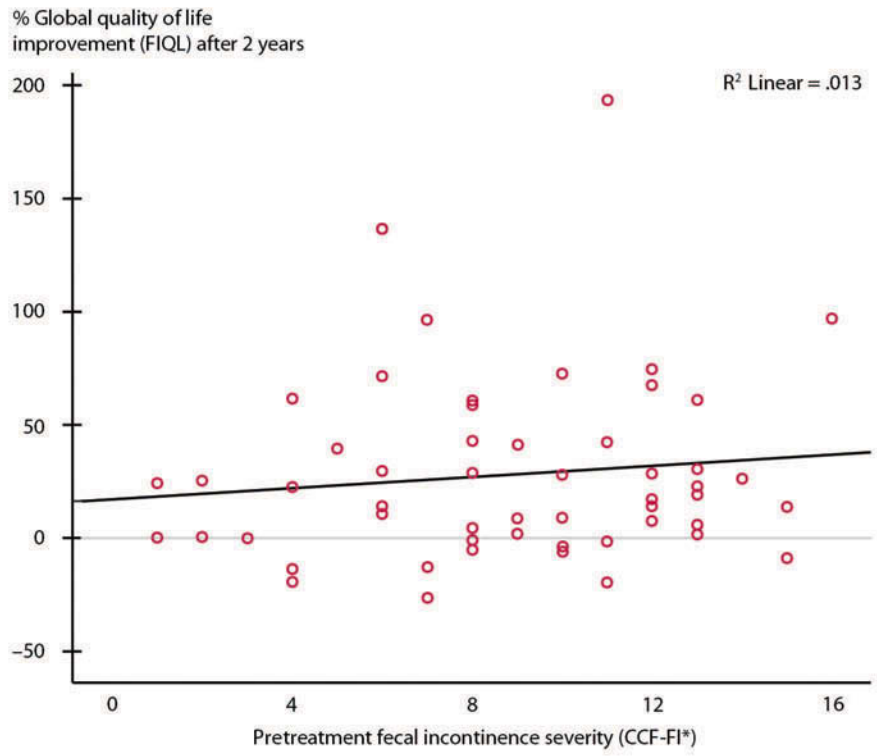

FIGURE 5. Relationship between quality-of-life improvement after 2 years and initial fecal incontinence severity; n = 53, median improvement (interquartile range) = 19.0% (0.2%–42.7%), r_s = .116, P = .407. CCF-FI = Cleveland Clinic Florida Fecal Incontinence Score; FIQL = Fecal Incontinence Quality of Life Scale. *Lifestyle component omitted.

between the 2 exercise regimens. However, 86% of participants had improved continence with 20% achieving complete fecal continence by the end of treatment and 38% reporting no fecal leakage 2 years later. Ninety percent of

TABLE 3. Number and duration of prescribed and performed exercises per day

	Exercise regime							
	Week 4				*Week 8*			
	SE (n = 37)		*RSE (n = 35)*		*SE (n = 35)*		*RSE (n = 34)*	
	n	*Duration*[a]	*n*	*Duration*[a]	*n*	*Duration*[a]	*n*	*Duration*[a]
Prescribed exercises (median)								
Pelvic floor, rapid	0	1.0	3	1.0	0	1.0	4	1.0
Anal sphincter, rapid	0	1.0	3	1.0	0	1.0	4	1.0
Pelvic floor, sustained	3	5.5	3	5.5	3	5.5	3	6.0
Anal sphincter, sustained	3	5.5	3	5.5	3	5.5	3	6.0
Repetition sets per day		6.5		6.5		6.5		6.0
Total prescribed per day (sec)		214.5		300.0		220.0		300.0
Performed exercises (median)								
Exercise performed per day (sec)		172.9		180.4		195.0		264.0
% Individual compliance with prescribed		80.6%		84.8%		85.7%		85.7%
Performed ≥ prescribed, n (%)		12 (32%)		10 (29%)		12 (34%)		14 (41%)
Performed < prescribed, n (%)		19 (51%)		20 (57%)		17 (49%)		17 (50%)
Data missing, n (%)		6 (16%)		5 (14%)		6 (17%)		3 (9%)
2-year follow-up		SE				RSE		
Participants reporting exercise performance		21/30 (70%)				20/28 (71%)		
Exercise performed per days (sec) (SE: n = 19; RSE: n = 17)		102.9[a]				44.3[a]		

SE = sustained exercise group; RSE = rapid and sustained exercise group.
[a]Duration in seconds.

participants were very satisfied with their treatment outcomes. Both continence and QOL scores improved significantly during treatment with the improvements maintained 2 years later.

Biofeedback enables patients to see the effect of squeezing, releasing, and resting the correct muscle on a computer screen, thereby producing high-quality contractions. Patients in this biofeedback program are advised to follow an exercise regimen of few and often until they are able to perform stronger and longer exercises less frequently (Table 3).[9] Although pelvic floor muscle training (PFMT) has been used to prevent and treat incontinence since the 1940s,[21] and biofeedback has been a prescribed FI treatment since 1974,[22] few studies have assessed the efficacy of PFMT alone for FI.[23] One recent randomized study showed manometric biofeedback with pelvic floor exercises was a more effective treatment for FI than pelvic floor exercises alone,[24] whereas another showed no difference between biofeedback and standard treatment.[25]

In this study, 86% of participants achieved improved continence within the treatment period, thus confirming the effectiveness of this holistic biofeedback program for FI. In a review of 46 studies of biofeedback treatment for FI, Norton[7] reported that 38 studies provided improvement rates, with only 7 showing better improvement than this study. The improved continence scores in this study also compare favorably with more recent studies.[26–29] It is difficult to compare QOL in FI studies that use different measurement tools; among the few biofeedback studies that have used the FIQL measurement tool, the scores and improvements are similar.[27,30] It is particularly difficult to compare this study with a Sri Lankan study where only 31 of 50 participants completed the survey and their QOL on each FIQL scale before treatment was very poor.[31]

The percentage of those cured, ie, no FI (38%, at the 2-year follow-up) compared less favorably with 19 of 46 biofeedback studies reviewed[7] which reported a higher cure rate than the present study, although only 26 provided cure rate data. Furthermore, the cure-rate in this study may have been lower than in earlier studies because of symptom tolerance, ie, choosing a personal cost–benefit ratio that substantially improved QOL with fewer exercises, rather than a complete cure with more exercises.

Rapid pelvic floor and anal squeeze exercises aim to improve muscle reaction time and increase muscle bulk, and submaximal sustained muscle squeezes aim to increase muscle strength and endurance.[9,12] Introducing rapid squeezes in this study population did not significantly affect patients' continence or QOL scores, either during the treatment period or at the 2-year follow-up. Objective manometry scores were not significantly changed during treatment and were not measured at the 2-year follow-up. Possible reasons for this lack of change are the short (5 weeks) duration of exercise practice, the fact that the rapid squeezes did not appear to be sufficiently different from the standard regimen to result in a significant difference in QOL or FI severity, and the patients in the pilot study that was used for sample size calculations were not representative of the heterogeneity of the study population. It may have been more appropriate to measure the impact of rapid squeezes by evaluating the time taken to reach baseline resting pressure between a set of rapid squeezes or the mean fatigue rate index.[32,33] However, the combination of both rapid and sustained exercises serves to increase patient awareness and control of these muscles.[21,34]

Patients who performed at least the prescribed number of exercises during the treatment period had significantly greater improvement in QOL and fewer incontinent episodes than those who performed fewer exercises than prescribed. However, at the 2-year follow-up, the QOL and continence scores of former compliers and noncompliers were similar, suggesting that the improvement in continence may be due to increased awareness and control, improved sensitivity, and decreased urgency achieved during treatment and maintained 2 years later. Although it requires several months of PFMT to improve the physiological condition of the musculature,[9,35] 2 years after treatment, many participants would be on a maintenance exercise program, performing fewer exercises daily. At the final treatment session patients were advised to increase the number of exercises to the previously prescribed level if they experienced a decline in continence on the maintenance program. Despite the lower number of maintenance exercises reported, there was continued improvement in FIQL and continence scores. The exercise/dose responses provide some evidence refuting the conclusion that biofeedback or exercises do not enhance the outcomes of treatment over standard care.[11]

QOL improvement was poorly correlated with FI severity, despite a significant trend, demonstrating that the biofeedback program was effective regardless of the initial level of severity. Poorer initial continence and FIQL scores were associated with better exercise compliance and greater improvement in QOL. Although this improvement may be due to regression to the mean, it could suggest that higher motivation encourages treatment compliance and thus a more successful outcome. The lifestyle component of the CCF-FI for this analysis was deducted to account for "regression to the mean" aspect,[36] ie, where QOL at the beginning was compared with QOL after treatment. At the 2-year follow-up, correlation between initial FI severity and QOL improvement was even less correlated, adding further evidence to the success of the program for all levels of FI severity.

A major limitation of this study was the heterogeneity of the population, which may have diluted the ability to

find significant differences, and the small sample size rendered it susceptible to a type 2 error. Better resourced programs may be able to study more homogenous groups. In addition, the results relied on patients reporting information about exercises performed. A subsequent study using home perinometers to objectively record exercise performance is underway. Moreover, this holistic program includes both anal and PFMT exercises that could reduce patient focus, whereas other studies test anal squeezes only. Finally, the highly mobile North Queensland population presents problems with enrollment and follow-up; it would be advantageous for future studies to collect more contact information to ensure better long-term follow-up.

CONCLUSIONS

More than 80% of patients attending this holistic biofeedback program achieved improvement in FI severity and QOL regardless of their initial continence score, with more than one third obtaining complete symptom relief. Compliance with the exercise program significantly improved patient outcomes. Adding rapid squeezes to the exercise regimen had little impact on FI severity or patient QOL.

REFERENCES

1. Ho YH, Muller R, Veitch C, Rane A, Durrheim D. Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. *Aust J Rural Health.* 2005;13:28–34.
2. Hawthorne G. Measuring Incontinence in Australia, Commonwealth of Australia, Canberra, 2006. http://www.health.gov.au/internet/main/publishing.nsf/Content/7F354DBFD2C9C565CA257210007F8DA6/$File/Meas%20Incont%20Aust%202006.pdf. Accessed December 6, 2010.
3. Kalantar JS, Howell S, Talley NJ. Prevalence of faecal incontinence and associated risk factors: an underdiagnosed problem in the Australian community? *Med J Aust.* 2002;176:54–57.
4. Lam TC, Kennedy ML, Chen FC, Lubowski D, Talley NJ. Prevalence of faecal incontinence: obstetric and constipation risk factors: a population based study. *Colorectal Dis.* 1999;1:197–203.
5. Bartlett L, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. *Tech Coloproctol.* 2007;11:251–257.
6. Australian Institute of Health and Welfare (AIHW). Australian incontinence data analysis and development. AIHW catalogue no. DIS 44. 2006:119.
7. Norton C, Kamm MA. Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults: a systematic review. *Aliment Pharmacol Ther.* 2001;15:1147–1154.
8. Sloots K, Bartlett L. Practical strategies for treating postsurgical bowel dysfunction. *J Wound Ostomy Continence Nurs.* 2009;36:522–527.
9. Sloots K, Bartlett L, Ho YH. Treatment of postsurgery bowel dysfunction: biofeedback therapy. *J Wound Ostomy Continence Nurs.* 2009;36:651–658.
10. DiNubile NA. Strength training. *Clin Sports Med.* 1991;10:33–62.
11. Norton C, Cody JD, Hosker G. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database Syst Rev.* 2006:CD002111.
12. Norton C, Chelvanayagam S. Methodology of biofeedback for adults with fecal incontinence: a program of care. *J Wound Ostomy Continence Nurs.* 2001;28:156–168.
13. Norton C, Chelvanayagam S. Conservative management of faecal incontinence in adults. In: Norton C, Chelvanayagam S, eds. *Bowel Continence Nursing.* Beaconsfield, UK: Beaconsfield Publishers Ltd; 2004:114–131.
14. Bartlett L, Ho YH. PTQ anal implants for the treatment of faecal incontinence. *Br J Surg.* 2009;96:1468–1475.
15. Rockwood TH, Church JM, Fleshman JW, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum.* 2000;43:9–17.
16. Rockwood T. The author replies. *Dis Colon Rectum.* 2008;51:1434.
17. Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum.* 1993;36:77–97.
18. Tuteja AK, Rao SS. Review article: recent trends in diagnosis and treatment of faecal incontinence. *Aliment Pharmacol Ther.* 2004;19:829–840.
19. Bharucha AE. Update of tests of colon and rectal structure and function. *J Clin Gastroenterol.* 2006;40:96–103.
20. Heaton K, Thompson W. Diagnosis. In: Heaton, K, Thompson, W, eds. *Irritable Bowel Syndrome.* Oxford: Health Press; 1999:27.
21. Kegel AH. Progressive resistance exercise in the functional restoration of the perineal muscles. *Am J Obstet Gynecol.* 1948;56:238–248.
22. Engel BT, Nikoomanesh P, Schuster MM. Operant conditioning of rectosphincteric responses in the treatment of fecal incontinence. *N Engl J Med.* 1974;290:646–649.
23. Norton C. Fecal incontinence and biofeedback therapy. *Gastroenterol Clin North Am.* 2008;37:587–604, viii.
24. Heymen S, Scarlett Y, Jones K, Ringel Y, Drossman D, Whitehead WE. Randomized controlled trial shows biofeedback to be superior to pelvic floor exercises for fecal incontinence. *Dis Colon Rectum.* 2009;52:1730–1737.
25. Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence. *Gastroenterology.* 2003;125:1320–1329.
26. Martínez-Puente Mdel C, Pascual-Montero JA, García-Olmo D. Customized biofeedback therapy improves results in fecal incontinence. *Int J Colorectal Dis.* 2004;19:210–214.
27. Naimy N, Lindam AT, Bakka A, et al. Biofeedback vs electrostimulation in the treatment of postdelivery anal incontinence: a randomized clinical trial. *Dis Colon Rectum.* 2007;50:2040–2046.
28. Beddy P, Neary P, Eguare EI, et al. Electromyographic biofeedback can improve subjective and objective measures of fecal incontinence in the short term. *J Gastrointest Surg.* 2004;8:64–72.
29. Mahony RT, Malone PA, Nalty J, Behan M, O'Connell PR,

O'Herlihy C. Randomized clinical trial of intra-anal electromyographic biofeedback physiotherapy with intra-anal electromyographic biofeedback augmented with electrical stimulation of the anal sphincter in the early treatment of postpartum fecal incontinence. *Am J Obstet Gynecol.* 2004;191: 885–890.

30. Davis KJ, Kumar D, Poloniecki J. Adjuvant biofeedback following anal sphincter repair: a randomized study. *Aliment Pharmacol Ther.* 2004;20:539–549.
31. Munasinghe BN, Geethani Rathnayaka MM, Parimalendran R, et al. Biofeedback with and without surgery for fecal incontinence improves maximum squeeze pressure, saline retention capacity and quality of life. *Indian J Gastroenterol.* 2008;27:5–7.
32. Marcello PW, Barrett RC, Coller JA, et al. Fatigue rate index as a new measurement of external sphincter function. *Dis Colon Rectum.* 1998;41:336–343.
33. Telford KJ, Ali AS, Lymer K, Hosker GL, Kiff ES, Hill J. Fatigability of the external anal sphincter in anal incontinence. *Dis Colon Rectum.* 2004;47:746–752.
34. Norton P. Aims of pelvic floor reeducation. In: Schussler B, Laycock J, Norton P, Stanton S, eds. *Pelvic Floor Re-education.* New York: Springer; 1994:121–123.
35. Griffin C, Dougherty MC, Yarandi H. Pelvic muscles during rest: responses to pelvic muscle exercise. *Nurs Res.* 1994;43:164–167.
36. Vickers AJ, Altman DG. Statistics notes: analysing controlled trials with baseline and follow up measurements. *BMJ.* 2001; 323:1123–1124.

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ORIGINAL RESEARCH

Biofeedback therapy for faecal incontinence: a rural and regional perspective

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ABSTRACT

Introduction: Faecal incontinence is the involuntary loss of liquid or solid stool with or without the patient's awareness. It affects 8–11% of Australian community dwelling adults and up to 72% of nursing home residents with symptoms causing embarrassment, loss of self-respect and possible withdrawal from normal daily activities. Biofeedback, a technique used to increase patient awareness of physiological processes not normally considered to be under voluntary control, is a safe, conservative first-line therapy that has been shown to reduce symptom severity and improve patient quality of life. The Townsville Hospital, a publicly funded regional hospital with a large rural catchment area, offers anorectal biofeedback for patients with faecal incontinence, constipation and chronic pelvic pain. The aim of this report is to describe the effect of the biofeedback treatment on the wellbeing of regional and rural participants in a study of biofeedback treatment for faecal incontinence in the Townsville Hospital clinic.

Methods: There were 53 regional (14 male) and 19 rural (5 male) participants (mean age 62.1 years) enrolled in a biofeedback study between January 2005 and October 2006. The program included 4 sessions one week apart, 4 weeks home practice of techniques learnt and a final follow-up reassessment session. Session one included documenting relevant history, diet, fibre, and fluid intake and treatment goals; anorectal function and proctometrographic measurements were assessed. Patients were taught relaxation (diaphragmatic) breathing in session two with a rectal probe and the balloon inserted, prior to inflating the balloon to sensory threshold. In session three, patients were taught anal sphincter and pelvic floor exercises linking the changes in anal pressures seen on the computer monitor with the exercises performed and sensations felt. Session four included improving anal and pelvic floor exercises, learning a defecation technique and receiving instructions for 4 weeks home practice. At the fifth session, home practice and bowel charts were reviewed and anorectal function was reassessed. Symptom severity and quality of life were assessed by surveying participants prior to sessions one and two and following session five. Patients were interviewed after session

five to determine their satisfaction with the therapy and the helpfulness of individual program components. They were mailed a follow-up survey 2 years later.

Results: Regional participants lived within 30 min drive of the clinic (median distance 8 km) while rural participants travelled up to 903 km (median 339 km, $p<0.001$) to attend the clinic. Faecal Incontinence risk factors were similar for rural and regional participants. Rural participants reported poorer general health ($p=0.004$) and their symptoms affected their lifestyle more negatively ($p=0.028$). Participants' incontinence ($p<0.001$) and quality of life ($p<0.001$) improved significantly over the treatment period. Improvement for rural participants over the course of treatment was marginally better than that of regional participants, although not significantly. More than 97% of patients reported that the biofeedback program was very/extremely helpful and all participants attending the final session reported that they would advise a friend in a similar situation not to wait, but seek help immediately, with more than half specifically citing the biofeedback program. Two years later regional participants' symptoms and quality of life continued to improve while rural participants' quality of life had regressed to pre-treatment levels.

Conclusions: For equivalent long term improvement in faecal continence and quality of life to be achieved in both regional and rural participants, an additional follow-up session with the biofeedback therapist, ongoing local support provided by continence advisors, or both, should be investigated for rural patients.

Key words: Australia, biofeedback, faecal incontinence, holistic program, quality of life, regional, rural.

Introduction

Faecal incontinence (FI), the involuntary loss of liquid or solid stool with or without the patient's awareness, may cause embarrassment, loss of self-respect, psychiatric disorders, and withdrawal from the community[1]. Little systematic research of this socially disabling condition has been conducted to determine either the true burden on individuals and communities or the results of treatment in northern Australia.

Community prevalence of FI has been reported to range between 8% and 11% in South Australia and New South Wales[2-4]. Faecal incontinence is a leading reason for nursing home placement in Australia where up to 72% of residents have the condition[5]. In studies conducted at the Colorectal and Urogynaecology outpatient clinics of the Townsville Hospital (TTH) in North Queensland more than one in five patients reported FI[1,6].

Biofeedback is a safe, conservative first-line treatment for FI[7]. The Townsville Hospital, a publicly funded regional hospital with an extensive rural catchment area, operates a nurse-run holistic biofeedback program for patients with FI, constipation or pelvic pain[8,9].

A Cochrane review of biofeedback for the treatment of FI found no evidence that any method of biofeedback or pelvic floor exercises provided better outcomes than any other conservative treatment method[10]. Standard care including diary and symptom questionnaire, structured assessment, patient teaching, emotional support, lifestyle modifications, management of FI and urgency control was a method that provided equivalent results[11]. When telephone assisted support for remote patients was compared with face-to-face biofeedback protocol for regional patients, no significant outcome differences were found[12].

This clinical study was designed to assess two exercise regimens, the efficacy of biofeedback program components for FI (L Bartlett, K Sloots; unpubl. data, 2005–2006) and whether treatment outcomes (ie FI severity or quality of life [QOL]) differed between rural and regional participants.

Methods

Participants

Clinic patients were eligible to participate in the study if their FI had persisted for at least 6 months and had failed to respond to standard treatment recommended by their GP. Further eligibility criteria included being at least 18 years of age and not pregnant; and having no terminal illness, mental illness or gastrointestinal stoma. Participants were referred by a colorectal surgeon following anorectal physiologic assessment including manometry and endoanal ultrasound. They attended the biofeedback program between January 2005 and October 2006 and signed informed consent forms.

Ethics

Ethics approval was granted by Townsville Health Service District Human Research Ethics Committee (47/04) and James Cook University (H1950). The Australian New Zealand Clinical Trials Registry number is ACTRN12610000258055.

Study procedure

Faecal incontinence patients on the TTH biofeedback waitlist were initially telephoned, had the study explained to them and were invited to participate. An information pack about the study and biofeedback treatment with appointment dates and a bowel chart were mailed to them. Treatment included 5 outpatient sessions: 4 at weekly intervals, 4 weeks home practice of techniques learnt, then an assessment session. Detail of the study procedure is provided (Fig1).

Participants met with the researcher immediately prior to the initial biofeedback session and completed a self administered FI questionnaire[1], including the 29 question Fecal Incontinence Quality of Life Scale (FIQL) survey tool[13]. The researcher completed the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI)[14] with them. Session one with the biofeedback therapist included documenting: relevant medical, surgical, obstetric and medication history; and bowel problems and habits. Diet, fibre, and fluid intake were discussed together with the aim of therapy and the establishment of treatment goals and instructions given to record food, fluid, supplement intake and medications used in the patient diary. Anorectal function and proctometrographic evaluation were assessed using clinic manometric equipment[15,16]. The therapist presented coping strategies and dietary advice[8]. The pre-treatment bowel chart was reviewed and comprehensive instructions were given to accurately record daily bowel accidents and toileted motions using the Bristol Stool Form Scale[17]. Immediately before session two, participants repeated the FIQL and CCF-FI with the researcher. The biofeedback therapist then reviewed the previous week's diary and bowel chart with the patient noting the impact of any dietary or coping modifications used, before instructing each patient in slow relaxation (diaphragmatic) breathing. Patients had the rectal probe and the balloon inserted, prior to inflating the balloon to sensory threshold. Lying in the supine position with one hand lightly resting on the upper abdomen to monitor diaphragmatic movement and rate of breathing, each participant practiced relaxation breathing for 5–10 min. Visual biofeedback was provided from the clinic computer monitor with verbal feedback from the therapist to improve the technique[9]. Patients were instructed to practise relaxation breathing at home at least twice per day and complete the bowel chart for the following week.

Before session three the biofeedback therapist was advised the exercise regimen to which the patient had been randomised; that is: standard exercises (sustained pelvic floor and anal squeeze exercises) or alternative exercises (rapid and sustained pelvic floor and anal squeeze exercises)[18].

In session three the previous sessions' therapy components were reviewed and amended. Anal sphincter and pelvic floor muscle exercises were taught according to the relevant exercise regimen. Participants were coached to link the changes in pressures seen on the computer monitor with the exercises performed and sensations felt. The aims of the exercises and techniques were to reduce urgency and frequency, and to improve sensitivity, anorectal co-ordination and continence. Patients were asked to perform their individual prescribed exercises at home (Fig2).

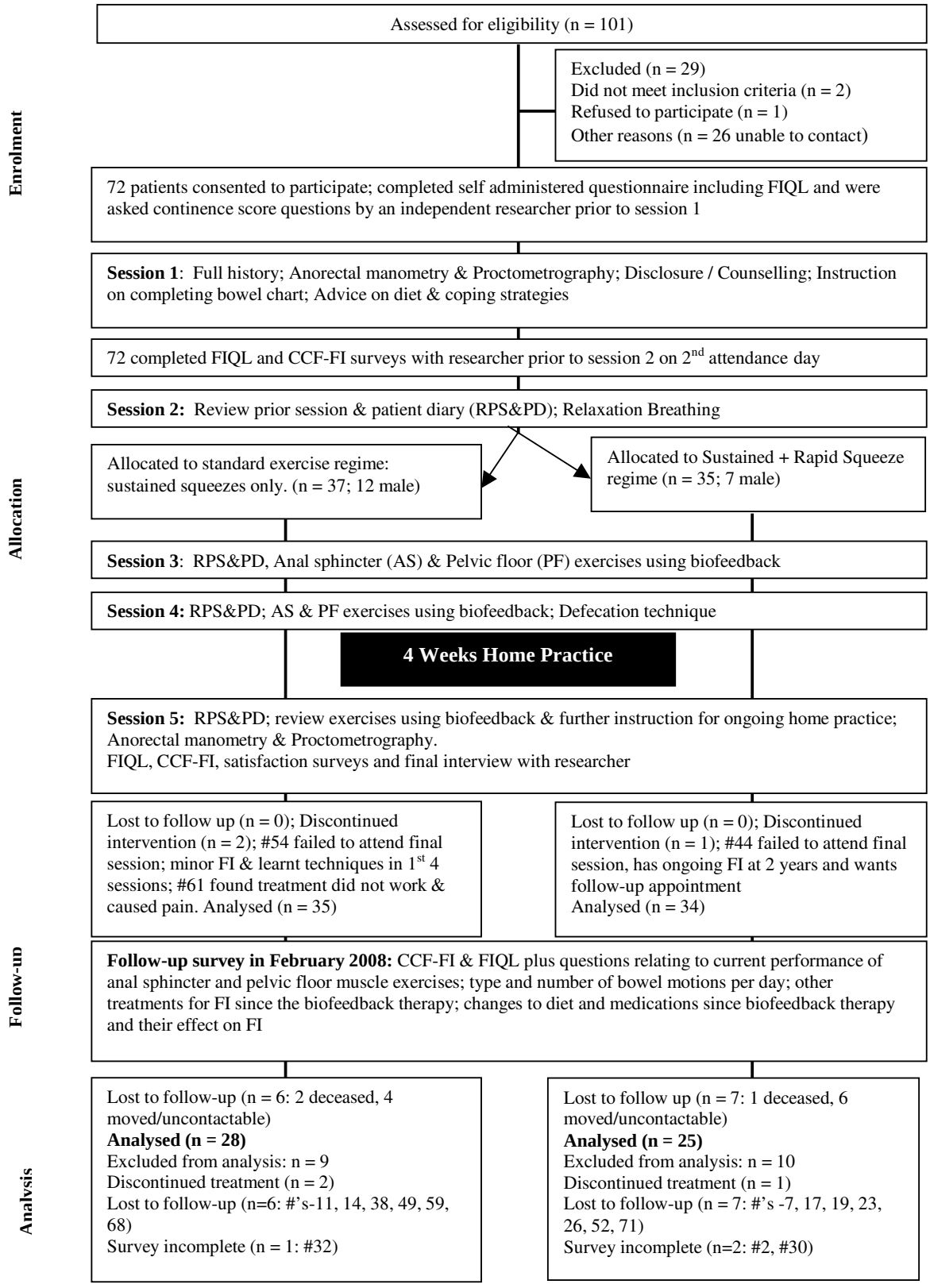

Figure 1: Participants' progress through the study

Figure 2: Rapid and sustained anal sphincter squeeze instruction.

A review of all components of previous treatment sessions (bowel charts, exercises, monitoring of dietary, medication, and fluid or supplement changes) was conducted by the biofeedback therapist in session four. The number and strength of prescribed exercises was increased as appropriate for the individual. A defecation technique, using a combination of the toileting position, relaxation breathing and evacuation technique was taught to assist with stool fragmentation and incomplete evacuation. Participants were then given written and verbal instructions on all components for their 4 week home practice.

At the fifth session, patients' home practice and bowel charts were reviewed with the biofeedback therapist; anorectal function was reassessed, and suggestions made for future improvements. Patients who felt they needed further support were able to book a follow-up appointment. At the completion of the fifth session the researcher reassessed severity of symptoms, the effect of FI on QOL and satisfaction with treatment outcomes; and also conducted a short semi structured interview to elicit participants' opinions about: the reasons for the delay in seeking treatment for FI; advice they would give fellow FI sufferers; suggestions they could provide to improve FI disclosure; and usefulness of a home biofeedback device.

In February 2008 all participants were mailed a follow-up survey.

Statistical analysis

Data were analysed on an intention-to-treat basis and patients who failed to complete the program were treated as missing. Numerical data are given as mean value and standard deviation (SD) or median value and interquartile range (IQR), depending on the distribution. Comparisons between characteristics were undertaken using χ^2 tests and χ^2 tests for trend, non-parametric Wilcoxon tests, and ***t***-tests. Statistical analyses were conducted using SPSS for Windows v17 (SPSS Inc; Chicago, IL, USA; www.spss.com). Throughout the analyses $p<0.05$ was considered statistically significant.

Results

Participants

Of 101 consecutive patients with FI referred for biofeedback, 72 participants (19 male), mean age 62.1 years (95%CI 38.3–85.9), were both eligible and consented to participate. Twenty participants (6 male) had previously

undergone bowel surgery, 12 for colorectal cancer (5 male). The surgery performed on these participants was: anterior resection, 11 (9 for low rectal carcinoma, 1 for diverticulitis, 1 for prolapse); segmental colectomy, 5 (carcinoma 1; diverticulitis 2; ischaemia of colon 1; rectal prolapse 1); and total proctocolectomy with ileal J-pouch anastomosis, 4 (carcinoma 2; diverticulitis 1; constipation 1). Eight participants (4 male) reported difficulty with rectal emptying. Of the 53 female patients, 38 (72%) had external anal sphincter defects; 13 had been surgically repaired prior to biofeedback referral, 26 had difficult vaginal deliveries requiring forceps or vacuum extraction, 5 women had vaginal repair surgery only and 10 women had both vaginal repair surgery and difficult vaginal deliveries. Fifty-three participants (14 male) lived within 30 min drive of the clinic (median 7.8 km, IQR: 5.7–12.0) while 19 (5 male) travelled up to 903 km (median 339 km, IQR: 136–388) from rural locations ($p<0.001$) to attend the clinic. Female participants were younger than male participants, and significantly so for regional residents ($p=0.044$, Table 1). Overall, participants had suffered from FI for a median duration of 24 months (IQR 18–48) with rural women reporting FI for a significantly shorter period before seeking treatment than their regional counterparts ($p=0.034$, Table 2). There were no adverse events as a result of treatment.

Baseline data

Pre-existing medical conditions and prior surgical history known to be risk factors for FI were similar for rural and regional participants. Rural participants reported poorer general health than regional participants ($p=0.004$) and lower QOL with regard to lifestyle ($p=0.028$, Table 3). Rural participants also presented with more severe FI than regional participants (CCF-FI, Table 3), significantly so for males ($p=0.044$).

Participants who failed to complete treatment

Sixty-nine participants completed all 5 treatment sessions (median duration 8 weeks). Three patients (all regional) failed to attend the final session: one with minimal FI (CCF-FI=1 and FIQL=4 for each scale) advised he had acquired sufficient skills in the first 4 sessions and did not need to continue; a second suffered post-surgery bowel dysfunction (following treatment for diverticulitis) and found the exercises exacerbated the pain and was not prepared to continue; the third did not provide a reason, but at the 2 year follow up requested further sessions with the biofeedback therapist.

Results at completion of treatment

Between the initial and final treatment sessions there were significant reductions in incontinent episodes (median of 4[1–11.5] to 1[0–2.3] per week, $p<0.001$) and stool frequency (median of 13[8–28] to 12[8–20] bowel motions per week, $p=0.007$) as recorded in participants' bowel charts. The CCF-FI reduced significantly (11.5 to 5.0, $p<0.001$) with 86% (59/69) of participants reporting improved continence. The FIQL subscales improved significantly (Lifestyle, 3.4 to 3.8; Coping, 2.3 to 3.1; Depression, 2.8 to 3.4; Embarrassment, 2.2 to 3.3; all $p<0.001$). There was also a significant improvement in the patients' subjective measures of their bowel control over the period of treatment, from a median of 3.0/10 (1.8–4) to a median of 7.5/10 (6.3–8.6), $p<0.001$, (0=worst, 10=best). Objective anorectal manometry and proctometrographic measures, undertaken at baseline and at the final biofeedback session were significantly improved for maximum squeeze pressure (median: 59.2–67.3 mmHg, $p<0.001$) and volume of initial sensation (median: 28–20 mL, $p=0.027$); marginally different for mean resting pressures (median: 34.6–32.0, p=ns [not significant]); and reduced for volume at first urge (median: 73.5–60 mL, p=ns) and maximum tolerable volume (150–125 mL, $p=0.023$). There were no significant differences in any objective measure between rural and regional participants (Table 4). Participants were very satisfied with the treatment program, with their median rating being 9 (7.5–10) out of a maximum of 10. They also rated individual components of the program from very to extremely helpful (Fig3).

Table 1: Participants' ages according to sex and location

Participant location	Age (years) (95% CI)						
	Male		Female			Total	
	n	Mean	*n*	Mean	*P*-value†	*n*	Mean
Regional	14	67.6 (49-86)	39	60.9 (36-85)	0.044*	53	62.7 (39-86)
Rural	5	64.2 (44-84)	14	59.2 (32-85)	0.411	19	60.5 (35-86)
Total	19	66.7 (48-85)	53	60.5 (35-85)	0.029*	72	62.1 (38-86)

†***P*** value comparing age by sex for rural and regional participants measured using the Wilcoxon unpaired test.
*****P*** value significant.

Table 2: Participants' duration of faecal incontinence according to sex and location

Participant location	Sex Median (IQR)						
	Male		Female			Total	
	n	FI Duration†	*n*	FI Duration†	*P*-value¶	*n*	FI Duration†
Regional	14	24 (13-39)	39	24 (18-60)	0.355	53	24 (17-52)
Rural	5	36 (25-96)	14	18 (13-27)	0.034*	19	24 (18-36)
Total	19	24 (15-48)	53	24 (18-52)	0.832	72	24 (18-48)

FI, Faecal incontinence.
†Duration in months; ¶***p*** value comparing duration of faecal incontinence by sex for rural and regional participants measured using the Wilcoxon unpaired test.
*****P*** value significant.

While improvement in rural participants' FIQL and CCF-FI scores over the course of treatment had been marginally better than that of regional participants, there were no significant differences in subjective or objective treatment outcomes between regional or rural participants at the final treatment session.

Final interview

At the session five interviews at least a quarter of participants (33% rural, 25% regional) reported they had sought help for their bowel leakage as soon as it occurred, while more than a third (45% rural, 40% regional) had sought help within 12 months. However, more than a quarter of participants (22% rural, 35% regional) did not seek help for more than a year. The reasons patients gave for the delay in obtaining treatment included: believing the problem would go away (26 patients, 6 rural); being too embarrassed to seek help (11 patients, 2 rural); being given poor advice by a GP, for example that nothing could be done, or that it was a normal problem after a 10lb baby (11 patients, 3 rural); just coping with the problem (13 patients, 2 rural); thinking FI was a normal part of aging (6 patients, 2 rural); believing they were the only one with the problem and not knowing it was treatable (5 patients, 2 rural); and experiencing previous unsuccessful treatments such as medication, anal stretching or fistula operations (11 patients, 5 rural).

More than 83% of the participants (15 rural, 45 regional) sought initial help from their GP, 4% (2 rural, 1 regional) from hospital doctors and 7% (2 rural, 3 regional) from their colorectal surgeon. Over 91% were directly referred to the colorectal surgeon; the remainder had colonoscopy or other investigations before referral to the colorectal surgeon.

Table 3: Quality of life and faecal incontinence severity over study period, according to location[13,19]

Location	Initial session (S1)		*P*	Final Session (S5)		*P*		2 Year follow up		*P*	
	n	Median (IQR)	S1†	*n*	Median (IQR)	(S1/S5)¶	Improvement compared[1]	*n*	Median (IQR)	(S1/2Yr)¶	Improvement compared†
FIQL: Lifestyle scale											
Regional	53	3.50 (2.9-3.9)	0.028*	50	3.80 (3.4-4.0)	<0.001*	0.523	44	3.90 (3.5-4.0)	0.004*	0.481
Rural	19	3.20 (1.7-3.6)		19	3.45 (3.0-3.9)	0.002*		11	3.30 (2.4-4.0)	0.033*	
FIQL: Coping/behaviour scale											
Regional	53	2.36 (1.5-2.8)	0.439	50	3.19 (2.6-3.6)	<0.001*	0.572	44	3.39 (2.7-4.0)	<0.001*	0.423
Rural	19	2.25 (1.2-2.7)		19	2.94 (2.3-3.5)	<0.001*		11	2.56 (1.7-4.0)	0.074	
FIQL: Depression/Self perception scale											
Regional	53	2.89 (2.3-3.6)	0.130	50	3.39 (3.2-3.7)	<0.001*	0.742	44	3.60 (3.1-3.8)	<0.001*	0.109
Rural	19	2.47 (2.2-3.4)		19	3.39 (2.8-3.6)	<0.001*		11	2.76 (2.2-3.8)	0.424	
FIQL: Embarrassment scale											
Regional	53	2.33 (1.7-3.0)	0.100	50	3.33 (3.0-3.7)	<0.001*	0.725	44	3.67 (2.8-4.0)	<0.001*	0.043*
Rural	19	2.00 (1.3-2.7)		19	3.33 (2.3-4.0)	0.001*		11	2.67 (1.7-4.0)	0.108	
CCF-FI											
Regional	53	11.0(7.5-14.0)	0.194	50	4.5(2.0-8.0)	<0.001*	0.353	43	3.0(1.0-8.0)	<0.001*	0.726
Rural	19	13.5(9.3-15.8)		19	5.0(3.0-8.0)	<0.001*		11	8.0(1.0-13.0)	0.059	

CCF-FI, Cleveland Clinic Florida Fecal Incontinence Score; FIQL, Fecal Incontinence Quality of Life Scale; IQR, inter-quartile range; ***n***, number of patients who completed questionnaires;

†Mann-Whitney unpaired test; ¶Outcome compared with baseline, Wilcoxon signed ranks test.
FIQL: Rockwood et al 2000 [13]; scales calculated as per Rockwood 2008 [19].
****P*** value significant.

Table 4: Anorectal physiology pre- and post-treatment, according to location

Assessment criteria	Treatment stage						Improvement	
	Initial Session			Final Session				
	n	Median (IQR)	*P*†	n	Median (IQR)	*P*¶	*P*§	
Mean Resting Pressure (mmHg)	72	34.6 (22-49)		68	32.0 (21-53)		0.071	
Regional	53	34.6 (22-49)	0.919	49	31.6 (22-49)	0.956	0.055	0.226
Rural	19	34.6 (18-54)		19	44.8 (18-55)		0.879	
Mean Squeeze Pressure (mmHg)	72	59.2 (38-90)		68	67.3 (46-111)		<0.001*	
Regional	53	57.3 (38-80)	0.220	49	64.0 (44-101)	0.204	0.001*	0.743
Rural	19	76.5 (32-128)		19	97.8 (49-127)		0.039*	
Volume of initial sensation (mL)	72	28.0 (18-40)		64	20.0 (15-30)		0.027*	
Regional	53	25.0 (18-38)	0.547	47	20.0 (15-30)	0.754	0.055	0.778
Rural	19	35.0 (18-45)		17	25.0 (15-38)		0.365	
Volume of first urge (mL)	72	73.5 (55-100)		63	60.0 (50-85)		0.058	
Regional	53	70.0 (50-103)	0.252	46	60.0 (50-85)	0.592	0.123	0.895
Rural	19	75.0 (60-100)		17	80.0 (48-98)		0.287	
Max tolerable volume (mL)	71	150 (110-180)		64	125.0 (96-165)		0.023*	
Regional	53	145.0 (108-180)	0.360	47	120.0 (95-160)	0.300	0.087	0.837
Rural	19	155.0 (139-193)		17	140.0 (105-178)		0.109	

†Baseline regional vs rural participants, Mann Whitney Unpaired test; ¶Completion: regional vs rural participants; Mann Whitney unpaired test; §Baseline vs completion: Wilcoxon signed ranks test; improvement: regional vs rural participants; Mann Whitney unpaired test.
****P*** value significant.

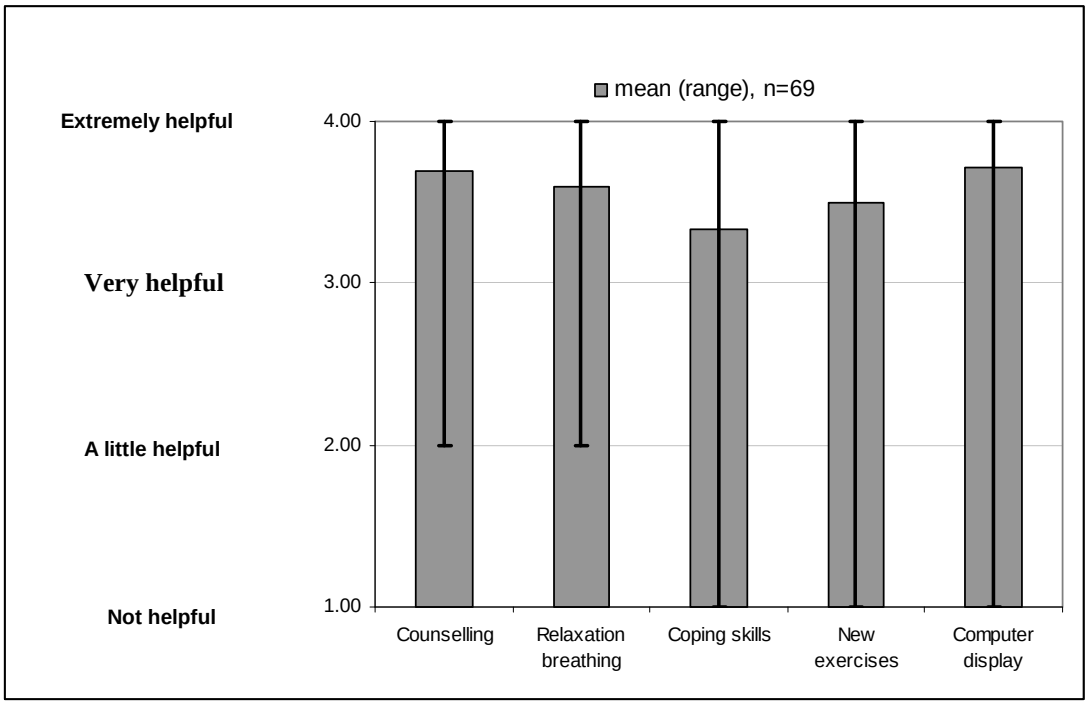

Figure 3: Participant rating of treatment components.

All participants attending the final session reported that they would advise a friend in a similar situation not to wait, but seek help immediately, with 53% specifically citing the biofeedback program, 14% their GP and 2% their specialist.

When asked for recommendations to facilitate patient disclosure of FI to doctors, suggestions included: asking patients directly about FI (54%: 14/19 rural; 22/48 regional, ***p***=0.039); listening to patients (39%: 10/19 rural; 16/48 regional); exhibiting empathy (24%: 8/19 rural; 8/48 regional, ***p***=0.028); providing advice about FI risk factors (24%, 6/19 rural; 11/48 regional); recommending biofeedback (18%: 2/19 rural; 11/48 regional); surveying patients (7%); shortening biofeedback waitlists (6%); providing private FI treatment facilities (6%); GP referral to specialist (4%); and more education about available treatment for FI for GPs and hospital doctors (12%: 4/19 rural; 4/48 regional). Patients were asked 'Would a confidential survey, completed in the waiting room that you handed straight to the GP aid discussion of this or other potentially embarrassing problems?' 86% of those asked (15/17 rural; 29/34 regional) said it was a good idea; 5 patients (1 rural) said they would not use it because they had good communication with their GP; one person thought a general consultation was too short to deal with an additional issue, but it could prompt a future discussion; while another would prefer to fill it in at home for use at a subsequent consultation.

More than 78% of participants had never seen information about FI in the community; those who had seen such information cited their pharmacy, community nurse, speakers at an older women's network, or the internet.

Over 97% of patients reported that the biofeedback program was very/extremely helpful. Five patients mentioned they were confident doing their exercises in the clinic with biofeedback, but were concerned that they were not doing them correctly at home. Of the 49 who were asked if they would be interested in trialling a home biofeedback device (with an anal sensor), 44 said they would because it would 'be motivating'; 'be good to see an improvement'; or

confirm they were doing the exercises correctly. Other qualitative feedback supported the satisfaction scores.

Two year follow up

Fifty-nine participants (12 rural) responded to the February 2008 survey. Thirteen participants were lost to follow up; three were deceased (1 rural) and ten (6 rural) could not be contacted. For regional participants FIQL and CCF-FI scores continued to improve (Table 3), although these results were not significantly different from their final treatment session, with 44% (19/43) reporting no faecal leakage. In contrast rural participants' FIQL scores had declined over time, and with the exception of the FIQL lifestyle scale (***p***=0.033) they were not significantly better than the pre-treatment scores (Table 3). For responding rural women, improvement in FI severity was maintained at the 2 year follow up; however, the three rural men who answered FI severity questions had reverted to pre-treatment levels. Only 18% (2/11) of rural respondents reported no faecal leakage. Of the 33 patients (9 rural) who reported still having some faecal leakage 14 (2 rural) reported mostly staining, 14 (6 rural) reported moderate faecal losses and 1 (regional) reported loss of a large amount of stool. There were no significant differences in results during the treatment program between the rural patients who responded to the 2 year questionnaire and those who did not.

Since completion of the biofeedback therapy, five survey respondents had sought additional help for their FI. New treatments included silicone anal implants (1 rural, 1 regional), stoma (2 rural) and additional medication (1 rural). Eleven participants (1 rural) requested further biofeedback sessions.

There were no significant differences between rural and regional participants in the number of exercises they performed or their confidence in performing these exercises, although rural participants performed their exercises more frequently. Additionally, stool type for rural participants was looser (***p***=0.033), they reduced food intake before going out (***p***=0.005), avoided travelling (***p***=0.045) particularly by aeroplane or train (***p***=0.002), and had more faecal urgency (***p***=0.048) and avoided visiting friends marginally more often (***p***=0.033). When asked directly, they reported feeling more depressed (***p***=0.048), felt less healthy (***p***=0.015), enjoyed life less (***p***=0.031), were more afraid to have sex (***p***=0.031), and were more likely to avoid going out to eat (***p***=0.001).

Discussion

The major findings of this study were that the biofeedback treatment program significantly improved continence and QOL for both regional and rural participants. While FI severity and QOL had continued to improve in regional participants 2 years later, for rural participants FI severity and QOL had regressed to pre-treatment levels.

Many people enjoy living in rural locations due to higher general wellbeing, personal safety and community connection[20]. Rural participants reported poorer general health than regional participants prior to treatment, which has been previously described in rural populations[21]. Poorer rural health has been linked to lower levels of education, employment and income, occupational risks, higher levels of hypertension, high cholesterol, asthma, diabetes and risky behaviour such as smoking and alcohol abuse, reduced access to health services, and driving long distances[21,22].

Rural female participants sought help earlier than regional women despite their FI severity scores not being significantly different. This is possibly due to the greater inconvenience to their lifestyle which involves more planning and the need to travel further, with less access to toilets. In comparison with regional participants, rural participants avoided travelling, going out to eat, visiting friends, were more afraid to have sex, were more depressed and enjoyed life less, all of which could explain their reduced sense of wellbeing.

While significant improvement of FI severity and QOL in both rural and regional participants was achieved during treatment, the QOL of rural participants failed to be

maintained over time. As there was no difference in exercise maintenance at the 2 year follow up, poorer rural QOL could be due to other reasons, such as a change in diet, reduced social interaction or lower tolerance of the impact of FI on QOL. Rural diet tends to be very different from urban diet, including more meat, biscuits and cakes[23]. Thus the dietary changes rural individuals needed to make may have been more difficult to maintain over the long term in their rural setting. Further research is required to investigate this issue.

Men and women who reside in rural northern Queensland may be required to perform heavy physical work (eg farmers and cane growers). Heavy lifting has been shown to put stress on pelvic floor muscles[24] which may in turn contribute to FI[25]. Additionally, in the long term, regular heavy physical work or the long working hours of primary producers may reduce the likelihood of performing prescribed exercises at the end of a tiring day, compared with people in more sedentary professions who can perform them at any time[26].

Disclosure of taboo subjects can be seen as socially risky, and people are less likely to disclose embarrassing information, particularly to close friends, relatives or respected associates such as GPs[27], especially if they believe the consequences will be negative[6,28]. By not admitting an urgent need to access toilet facilities to prevent bowel leakage, rural participants' social or informal support networks may fail[22]. To maintain post-treatment QOL improvements, rural participants may require referral to a counsellor at the end of biofeedback treatment, or longer term biofeedback clinic support by way of a home biofeedback device, a telephone helpline, newsletter, or webpage.

Participants reported that disclosure of FI to their doctor was embarrassing and many delayed seeking help. Most thought that an 'embarrassing topic survey tool' available in their GP's surgery may have assisted them to disclose their FI earlier, or the GP to ask patients with risk factors whether they had FI, directly and with empathy. They felt this would enable disclosure and facilitate treatment, while maintaining the professional doctor–patient relationship. An embarrassing topic survey tool is currently being assessed.

The short treatment program (5 x 1.5 hour sessions over 8 weeks), which is comparable with other biofeedback programs[7,29], may not be sufficiently supportive for rural patients in the long term. A similar program in Sydney, Australia with 5 monthly sessions, used telephone assisted support between initial and final face-to-face sessions for rural/remote patients and found no difference in results between that method and full clinic attendance for regional participants[12]. The treatment duration of that study was twice the length of this study, even though the number of sessions was equivalent. Advantages of the longer treatment duration may include greater time for patients to practise techniques learnt, greater opportunity to present problems to the therapist and for the therapist to customise treatment. However this may be at the cost of building a strong therapist–client relationship, patient focus and motivation in the short term.

Conclusion

For rural participants to maintain similar long-term improvement in continence and QOL to regional participants, an additional follow-up session with the biofeedback therapist and ongoing local support by continence advisors should be investigated for these patients. A telephone helpline, newsletter, or webpage may also be beneficial.

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References

1. Ho YH, Muller R, Veitch C, Rane A, Durrheim D. Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. ***Australian Journal of Rural Health*** 2005; **13(1):** 28-34.

2. Kalantar JS, Howell S, Talley NJ. Prevalence of faecal incontinence and associated risk factors; an underdiagnosed problem in the Australian community? ***Medical Journal of Australia*** 2002; **176(2):** 54-57.

3. Lam TCF, Kennedy ML, Chen FC, Lubowski D, Talley NJ. Prevalence of faecal incontinence: obstetric and constipation risk factors: a population based study. ***Colorectal Disease*** 1999; **1:** 197-203.

4. Hawthorne G. ***Measuring Incontinence in Australia 2006***. Canberra: Commonwealth of Australia; 2006.

5. Australian Institute of Health and Welfare. ***Australian incontinence data analysis and development***. AIHW cat no DIS44. Sydney, NSW: AIHW, 2006; 119.

6. Bartlett L, Nowak M, Ho YH. Reasons for non-disclosure of faecal incontinence: a comparison between two survey methods. ***Techniques in Coloproctology*** 2007; **11(3):** 251-257.

7. Norton C, Kamm MA. Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults--a systematic review. ***Alimentary Pharmacology & Therapeutics*** 2001; **15(8):** 1147-1154.

8. Sloots K, Bartlett L. Practical strategies for treating postsurgical bowel dysfunction. ***Journal of Wound, Ostomy, and Continence Nursing*** 2009; **36(5):** 522-527.

9. Sloots K, Bartlett L, Ho YH. Treatment of postsurgery bowel dysfunction: biofeedback therapy. ***Journal of Wound, Ostomy, and Continence Nursing*** 2009; **36(6):** 651-658.

10. Norton C, Cody JD, Hosker G. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. ***Cochrane Database of Systematic Reviews*** 2006; **3:** CD002111.

11. Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence. ***Gastroenterology*** 2003; **125(5):** 1320-1329.

12. Byrne CM, Solomon MJ, Rex J, Young JM, Heggie D, Merlino C. Telephone vs. face-to-face biofeedback for fecal incontinence: comparison of two techniques in 239 patients. ***Diseases of the Colon and Rectum*** 2005; **48(12):** 2281-2288.

13. Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. ***Diseases of the Colon and Rectum*** 2000; **43(1):** 9-16.

14. Jorge JM, Wexner SD. Etiology and management of fecal incontinence. ***Diseases of the Colon and Rectum*** 1993; **36(1):** 77-97.

15. Tuteja AK, Rao SS. Review article: Recent trends in diagnosis and treatment of faecal incontinence. ***Alimentary Pharmacology & Therapeutics*** 2004; **19(8):** 829-840.

16. Bharucha AE. Update of tests of colon and rectal structure and function. ***Journal of Clinical Gastroenterology*** 2006; **40(2):** 96-103.

17. Heaton K, Thompson W. Diagnosis. In: K Heaton, W Thompson (Eds). ***Irritable bowel syndrome***. Oxford: Health Press, 1999; 27.

18. Bartlett L, Sloots K, Nowak M, Ho Y-H. Biofeedback for faecal incontinence: a randomized control study comparing exercise regimen. ***Diseases of the Colon and Rectum*** 2011; (in press).

19. Rockwood T. The author replies. ***Diseases of the Colon and Rectum*** 2008; **51(9):** 1434.

20. Cummins R, Davern M, Okerstrom E, Lo S, Eckersley R. ***Australian Unity Wellbeing Index: special report on city and country living***. Report 12.1. Geelong, VIC: Deakin University, 2005.

21. Australian Institute of Health and Welfare. ***Australia's health 2010***. Australia's Health series no. 12. Cat. no. AUS 122. Canberra, ACT: AIHW, 2010.

22. Davis S, Bartlett H. Healthy ageing in rural Australia: issues and challenges. ***Australasian Journal on Ageing*** 2008; **27(2):** 56-60.

23. Dobson A, Mishra G, Brown W, Reynolds R. Food habits of young and middle-aged women living outside the capital cities of Australia. ***Australian and New Zealand Journal of Public Health*** 1997; **21(7):** 711-715.

24. Jorgensen S, Hein HO, Gyntelberg F. Heavy lifting at work and risk of genital prolapse and herniated lumbar disc in assistant nurses. ***Occupational Medicine*** 1994; **44(1):** 47-49.

25. Norton C, Chelvanayagam S. Causes of faecal incontinence. In: C Norton, S Chelvanayagam (Eds). ***Bowel Continence Nursing***. Beaconsfield: Beaconsfield Publishers 2004; 23-32.

26. O'Kane GM, Craig P, Black D, Sutherland D. Riverina men's study: a preliminary exploration of the diet, alcohol use and physical activity behaviours and attitudes of rural men in two Australian New South Wales electorates. ***Rural and Remote Health*** **8:** 851. (Online) 2008. Available: http://rrh.deakin.edu.au (Accessed 11 February 2011).

27. Bartlett L, Nowak M, Ho YH. Impact of fecal incontinence on quality of life. ***World Journal of Gastroenterology*** 2009; **15(26):** 3276-3282.

28. White T. Consumer Disclosure and Disclosure Avoidance: A Motivational Framework. ***Journal of Consumer Psychology*** 2004; **14:** 1441-1451.

29. Heymen S, Jones KR, Ringel Y, Scarlett Y, Whitehead WE. Biofeedback treatment of fecal incontinence: a critical review. ***Diseases of the Colon and Rectum*** 2001; **44(5):** 728-736.

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ORIGINAL ARTICLE

Biofeedback therapy for symptoms of bowel dysfunction following surgery for colorectal cancer

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Abstract

Background Following colorectal cancer (CRC) surgery, up to 60% of patients experience post-surgery bowel dysfunction (PSBD). This retrospective review aimed to evaluate biofeedback therapy with regard to patients' symptoms of fecal incontinence (FI) and stool frequency.

Methods Patients with symptoms including frequency, urgency, FI, incomplete evacuation, failure to respond to dietary, medication or standard pelvic floor exercises (C6 months) underwent biofeedback therapy between 2003 and 2006. Patients attended 3–4 sessions 1 week apart incorporating: anorectal function assessment; Fecal Incontinence Quality of Life (FIQL) and severity questionnaires; suggested coping strategies; dietary advice; bowel, food and exercise diary training; relaxation breathing; evacuation techniques; anal and pelvic floor muscle exercises using computerized visual feedback; and were reassessed at a final session following 4 weeks of home practice.

Results Nineteen CRC PSBD patients [anterior resection (3); ultra-low anterior resection (10); segmental colectomy (2); and proctocolectomy (4)], mean age: 64.1 (95% CI: 47.0–81.3) years, participated. FIQL scales improved significantly for lifestyle, coping and embarrassment but not depression. Incontinence severity and number of bowel motions significantly decreased. Satisfaction with results of therapy was high. Subjective bowel control rating improved. FIQL scores further improved 2 years later.

Conclusion The holistic biofeedback protocol for PSBD in CRC patients is successful in the short and medium term.

Keywords Colorectal cancer · Fecal incontinence · Patient satisfaction · Post-surgery bowel dysfunction · Quality of life

Introduction

More Australians are now surviving colorectal cancer (CRC) [1, 2]. The usual treatment for CRC in Australia is surgical excision, with or without radiation and/or chemotherapy [3]. These surgical procedures include anterior resection, ultra-low anterior resection, colectomy and proctocolectomy [4]. Up to 60% of patients, who undergo this sphincter preserving surgery for CRC, experience some post-surgery bowel dysfunction (PSBD) [5, 6]. Defecation problems occur in 28% of patients who require low anterior resection; 25% following sigmoid colectomy and to a lesser degree (4–15%) following more proximal segmental bowel resections, such as right hemicolectomy [7]. PSBD symptoms include frequent bowel motions, urgency, excessive flatus, incomplete bowel evacuation, constipation and in 37.5% of patients, fecal incontinence [8].

Fecal incontinence (FI), the loss of control of the passage of liquid or solid stool, can have a profoundly negative impact on a person's quality of life and their social and economic status. Estimates of prevalence of FI in the

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Australian population range from 5.5 to 20% [9] with this condition being reported as a problem for 35–39% of patients who have undergone surgery for CRC [10, 11].

While the majority (61–65%) of patients who have surgery for CRC overcome PSBD with or without standard medication, pelvic floor exercises, changes in diet, medication and supplements, within 6–12 months [12], those whose condition does not resolve have limited treatment options, leaving their quality of life severely compromised. The most conservative of these options is biofeedback therapy, with more invasive treatments including injectable silicone biomaterial, sacral nerve stimulation, or a stoma as a final resort.

Biofeedback has previously been shown to improve symptoms of FI [13, 14]. Biofeedback increases the patient's awareness and control of physiological responses and functions and assists with learning the techniques for muscle strengthening and control, increased muscle–nerve coordination, and improved more effective stool elimination [15, 16].

The aim of this retrospective review was to examine the effectiveness of biofeedback therapy for the treatment of PSBD with regard to the symptoms of FI and stool frequency following CRC surgery.

Methods

Participants

Nineteen patients (10 men), mean age 64.1 (95% CI: 47.0–81.3) whose surgery for CRC had resulted in bowel dysfunction including frequency, urgency, excessive flatus, incomplete evacuation and FI, were referred by a colorectal surgeon for biofeedback therapy. While the median (IQR) duration of PSBD symptoms (since surgery) reported by patients was 18 (12–24) months, women presented for biofeedback treatment earlier at 18 (12–24) months post-surgery compared with men at 24 (12–42) months, although this difference was not statistically significant. These patients' FI had failed to respond to treatment by conservative dietary or medication methods or by standard pelvic floor exercises over a 6–12 month period. All participants attended the Townsville Hospital Anorectal Biofeedback Program between July 2003 and July 2006. The surgery performed on these patients was as follows: curative anterior resection for upper rectal carcinoma (3); ultra-low anterior resection for mid and low rectal carcinoma (10); segmental colectomy (2, both right hemicolectomy); or total proctocolectomy with ileal J pouch anal anastomosis (4). Informed consent was signed by all patients and ethical approval was received from the human research ethics committees of the Townsville Hospital and James Cook University.

Biofeedback program

Participants attended 4–5 outpatient treatment sessions (mean duration 7 weeks). The initial session included recording relevant medical, surgical, obstetric and medication history. Bowel habits and problems, usual diet, and dietary fiber, alcohol, and fluid intake were discussed together with the aim of therapy and the establishment of personal treatment goals.

Pre- and post-treatment anorectal function was assessed using a Gaeltec catheter with a single solid-state pressure transducer (Gaeltec Ltd., Dunvegan, Isle of Skye, Scotland) and Neomedix Acquidata System (Acquiprocessor Model No. ML785NM, Acquiamplifier Model No. 601.819) with Uromac/Urotrak (Powerlab v 5.2.2) and anorectal computer program (Neomedix, Hornsby, Sydney, Australia). The anal canal length, the mean anal sphincter resting pressure and maximum voluntary contraction squeeze pressure were recorded. A latex balloon positioned in the rectal vault was inflated to elicit the rectosphincteric inhibitory reflex and to determine the intra-rectal volume required to produce an initial sensation, the first urge to evacuate and the maximum tolerated volume [15].

Patients also completed questionnaires about the severity of their FI [17] and the impact of FI on their quality of life [18, 19]. The therapist suggested coping strategies including timing and dosage of anti-diarrheal medications; defecation delay strategies; clean-up kits; continence aids/products; and access to toilet maps. The therapist also gave dietary advice including the impact of fat, fiber, alcohol, caffeine, chocolate, spicy foods, drinks with a low pH and some chemical additives, as well as avoiding rapidly drinking large volumes of hot or cold fluid, especially with meals, together with possible use of cholestyramine and supplements [15]. Participants were also given a diary in which to record stool type, daily bowel accidents and toileted motions; food intake; medication used; and prescribed exercises performed (Fig. 1).

The Townsville Hospital Anorectal biofeedback treatment protocol has been adapted from previously used protocols (Fig. 2) [20, 21]. During sessions 2–4, computer-assisted visual biofeedback and verbal feedback from the therapist were used to instruct patients and monitor their progress in: relaxation breathing (to decrease anxiety and regulate intestinal motility in order to improve bowel function); evacuation techniques; and anal sphincter and pelvic floor muscle exercises. Anal sphincter and pelvic floor exercises incorporated both rapid contractions (fast twitch) to improve muscle bulk and reaction time and sustained contractions and to increase muscle strength and endurance [20]. The eventual aim was for each patient to achieve a set of exercises consisting of 10 rapid squeezes, 1 s apart; 4 or 5 half-strength sustained squeezes and one or

Fig. 1 The Townsville Hospital—clinical measurements unit

The Townsville Hospital – Clinical Measurements Unit
BOWEL CHART
(Incontinence)

NAME: B05:015 Date started: 30 March 2005

** Relaxation breathing: 5-10 minutes, 2-4 times per day*
** Prescribed exercises: 5 sets per day; 1 set = 6 rapid anal squeezes; 4 x sustained anal squeezes (6-8 seconds) and 6 rapid pelvic floor squeezes; 4 x sustained pelvic floor Squeezes (6-8 seconds)*

Date	Time	Accident S=Stain M=Mo derate L=Large	Bowel Motion Type *(Bristol Stool Form Scale)*	Medication**/diet * *(Diet-Dairy / Metamucil) Record milk or cheese Metamucil (1 tsp in water x 1/day before food*	Exercises	
					Relaxation breathing	PFME / Anal Squeezes
30.03.05	5.30 10.30 12.30 16.00 19.30 20.00	S M S	6 6 5 5 6 6	Cranberry Osteo Relief Zocor *(Simvastatin)*	✓ ✓	✓ ✓ ✓ ✓ ✓ ✓ ✓
31.03.05	7.30 11.00 16.30 19.40	L S	6 6 5 6	"	✓ ✓	✓ ✓ ✓ ✓ ✓ ✓

* Hand written
** As prescribed by patients medical practitioner

two maximum-strength sustained squeezes each held for 8–10 s with 10 s rest between sustained squeezes, practiced regularly to achieve a minimum of 40 sustained contractions per day. However, dependent on individual patient's ability, the prescribed number could be as few as 2 or 3 rapid squeezes and 1 or 2 half-strength sustained squeezes per set, practiced more frequently to still achieve at least 40 sustained contractions per day [22]. Biofeedback was also used to modify rectal sensitivity and assist with bowel training techniques to improve muscle–nerve coordination and elimination habits [20, 22].

Patients then undertook 4 weeks of daily home practice of their individually prescribed regimen of relaxation, muscle squeezes and evacuation techniques learnt in sessions 1–4. At the final session, patients' anorectal function, severity of symptoms and the effect of FI on quality of life were reassessed and their satisfaction with progress recorded. From 2005, patients also answered questions about how helpful they found specific components of therapy.

Twelve participants were followed up with a short survey in February 2008, an average of 2.4 years after treatment.

Evaluation instruments

The Continence Grading Scale (CS) developed by Jorge and Wexner [17] was administered in a standardized manner by the attending therapist. The CS contains five questions on solid and liquid fecal soiling, flatus control, pad wearing and adjustments to daily living made necessary by their FI. A total score of zero reflects complete continence, and a score of 20 reflects the most severe incontinence.

Patients also completed a self-administered fecal incontinence questionnaire [10] containing questions on patient demographics (3 questions); alcohol consumption (2 questions); pre-existing medical conditions (10 questions); and prior surgical history (5 questions), which are all risk factors for FI. Subsequent questions related to the frequency (2 questions), severity (3 questions) and management (9 questions) of FI, and a further 29 questions sought information about the impact of FI on their quality of life using the Rockwood Fecal Incontinence Quality of Life Scale (FIQL) [18, 19]. The FIQL asks questions about selected aspects of a person's quality of life which may be affected by FI. The FIQL is divided into four subscales that

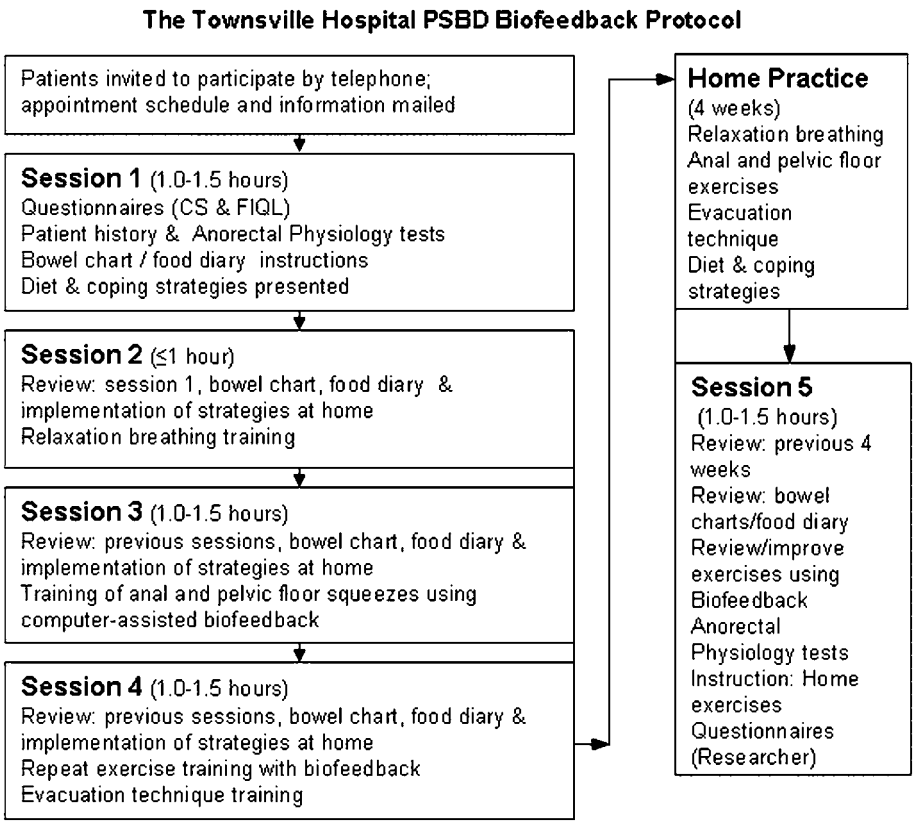

Fig. 2 The Townsville Hospital PSBD biofeedback protocol

measure the impact of FI on lifestyle; coping/behavior; embarrassment; and depression/self perception, with possible scores ranging from 1 to 4, where 1 represents a very low functional quality of life status and 4 represents very high functional quality of life status.

Satisfaction with the results of therapy was measured using a visual analog scale (VAS) where 0 = unsatisfied and 10 = extremely satisfied. Further information about satisfaction with treatment was sought from the last 12 patients treated by an independent researcher after the final treatment session. Five components of therapy were evaluated to determine how helpful they were: discussing the problem with the therapist; learning and using the relaxation breathing technique; coping strategies suggested by the therapist; learning and using the anal sphincter and pelvic floor exercises; and viewing the representation of exercise performance on the computer screen. Scoring for all these questions was 1 = not helpful, 2 = a little helpful, 3 = very helpful and 4 = extremely helpful. At the completion of the final session, patients were asked to rate their bowel control both following and prior to the commencement of the treatment, using a 0–10 VAS where 0 = very poor, 5 = OK, 10 = extremely good.

The follow-up survey included the CS and FIQL and other questions related to the following: current practice of anal sphincter and pelvic floor muscle exercises; type and number of bowel motions per day; other treatments for FI since the biofeedback therapy; changes to diet and medications since biofeedback therapy and their effect on FI.

Statistical analysis

Age is presented using mean and 95% confidence intervals (95% CI). Satisfaction with components of treatment is presented using mean values ± SE of the mean. Bowel function, satisfaction with results of therapy, CS, FIQL subscales and anorectal physiological parameters are presented using median and inter-quartile range (IQR).

Anorectal physiological measurements, FIQL subscales, CS, number of incontinent episodes per week and number of bowel motions per day were compared before and after FI treatment using the Wilcoxon rank-sum test. Subjective ratings of bowel control before and after treatment were compared using the Student's t test. A significance level of 0.05 was adopted a priori.

Results

All patients completed 4–5 sessions (mean duration 7 weeks). Their CS improved from 9 (7–12) to 6 (3–8), ($P = 0.001$), specifically reduced flatus ($P = 0.017$) and reduced solid and liquid fecal leakage ($P = 0.001$); however, there was no significant difference in the incontinent

episodes recorded in patient diaries between the week prior to treatment commencement and final week of treatment. There was a significant reduction in stool frequency (P = 0.003) and initial median stool consistency of 5 on the Bristol Stool Form Scale marginally improved to 4.5 over the course of the treatment as reported in patient diaries. The quality of life subscales showed significant improvement for lifestyle (P = 0.001), coping (P = 0.001) and embarrassment (P = 0.001). However, the depression subscale, which reflected little depression initially, was unchanged following treatment (Table 1).

There was a significant improvement (P = 0.006) in the patients' subjective measures of their bowel control over the period of treatment, from a median of 3.3 (IQR 1.3–5) to a median of 7.3 (IQR 6–8.8) (Table 1). However, objective anorectal manometry measurements, undertaken before and after the biofeedback treatment were not significantly changed (Table 2).

Overall satisfaction rating for treatment was high with a median ranking of 8.0 (IQR 7–9.75) out of a maximum possible score of 10. Satisfaction levels with individual components of biofeedback treatment were also high, particularly the relaxation breathing, counseling aspects and the computer-assisted visual display provided while learning the pelvic floor and anal squeeze exercises (Fig. 3). Patients also found guidance in coping strategies such as diet modification, fluid and supplement intake, and urgency control very helpful.

Twelve of the nineteen participants were followed up in February 2008. All final session median FIQL scores improved further, although this was not statistically significant (Lifestyle: 3.8; Coping: 3.3; Depression: 3.6; Embarrassment: 3.7). The CS marginally worsened from a median of 6 to a median of 7 (P [0.05) although it remained better than at baseline (median = 9). Nine (75%) patients continued performing their exercises, while the remaining three had forgotten how to do the exercises, with one requesting a follow-up session. At this two-year follow-up, median bowel motions were 4.25 per day and were of type 4 on the Bristol Stool Scale. One patient had been prescribed Salazopyrin to ease their diarrhea, but no others had received further treatment.

Discussion

The major findings of this review were that participants with PSBD following surgery for CRC achieved significant reduction in their symptoms after therapy using computer-guided biofeedback. There were significant reductions in the overall severity and the frequency of solid and liquid FI (using the CS) and in the number of bowel motions toileted per day. Participants also reported an improvement in their QOL, with significant improvements in the lifestyle, coping and embarrassment subscales of the FIQL. Patients reported being highly satisfied with the improvement in

Table 1 Bowel function and quality of life before and after biofeedback treatment

Parameter	Median (IQR)		P value[a]
	Initial session (n = 19)	Final session (n = 19)	
FI quality of life subscales[b]			
Lifestyle	2.8 (2.1–3.7)	3.5 (3.0–4.0)	0.001
Coping	2.1 (1.7–3.0)	2.9 (2.3–3.5)	0.001
Depression	3.4 (2.6–3.7)	3.3 (3.0–3.6)	0.828
Embarrassment	3.0 (1.7–3.0)	3.3 (2.7–4.0)	0.001
Continence grading scale[c]			
Total score (max 20)	9.0 (7.0–12.0)	6.0 (3.0–8.0)	0.001
Solid ? liquid FI score (max 8)	4.0 (1.0–5.0)	2.0 (1.0–3.0)	0.001
Flatus score (max 4)	3.0 (1.0–4.0)	0.0 (0.0–3.0)	0.017
Patient diary (week prior)			
Incontinent episodes	1.0 (0.0–6.5)	0.5 (0.0–3.0)	0.183
Bowel motions (per day)	5.0 (2.9–8.6)	2.9 (1.9–4.4)	0.003
Bristol stool form scale	5.2 (4.0–6.2)	4.5 (4.0–5.3)	0.213
Final interview			
Subjective bowel rating (max 10)	3.3 (1.3–5.0)	7.3 (6.0–8.8)	0.006

[a] P value was measured using the Wilcoxon rank-sum test; n number of patients, IQR inter-quartile range

[b] FIQL, Rockwood et al. [18]; scales calculated as per Rockwood [19]

[c] Jorge and Wexner continence grading scale [17]

Table 2 Anorectal physiological measurements before and after biofeedback treatment

	Median (IQR)		P value[a]
	Initial session (n = 19)	Final session (n = 19)	
Anal canal			
Mean resting pressure (mmHg)	29.4 (20.6–47.1)	29.4 (22.1–38.2)	0.913
Maximum squeeze pressure (mmHg)	66.2 (34.6–89.0)	82.4 (50.0–116.9)	0.235
Rectum			
Volume of initial sensation (ml)	40.0 (20.0–55.0)	25.0 (16.0–45.0)	0.135
Volume at first urge (ml)	80.0 (60.0–110.0)	60.0 (45.0–90.0)	0.097
Maximum tolerable volume (ml)	105.0 (100.0–150.0)	115.0 (85.0–165.0)	0.635

[a] P value was measured using the Wilcoxon rank-sum test; n number of patients, IQR inter-quartile range

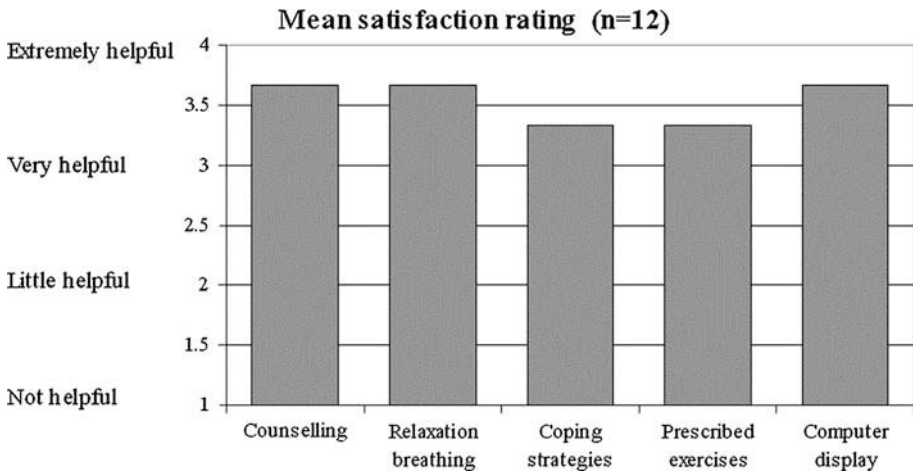

Fig. 3 Mean satisfaction rating (n = 12)

bowel control, their improvement over the period of treatment and with the overall program. This improvement was sustained for more than 2 years following completion of treatment. To our knowledge, this is the first report of biofeedback for PSBD in CRC patients in Australia.

This work confirms the effectiveness of biofeedback for the treatment of general FI found in earlier studies [13]. Whereas Allgayer et al. [12] demonstrated improvement following biofeedback treatment in PSBD CRC patients who had irradiation plus surgery or surgery alone was sustained after 1 year, this review shows that benefits of biofeedback in CRC patients can be sustained or further improved more than 2 years after biofeedback treatment.

Both objective and subjective measures were used to evaluate the data. Objective measures such as anorectal manometry and endoanal ultrasonography have been found to have major limitations as surrogate measures for FI for reasons such as poor sensitivity and specificity [23, 24]. Physiological studies, while helpful in diagnosing the cause of FI and indicating possible treatment options, provide little value as a measurement tool. Thus, Baxter et al. [23] in their landmark paper on FI measurement stated that FI must be measured by subjective assessment. The subjective measures of severity and impact on quality of life used here to evaluate FI provided statistically significant results unlike the objective anorectal physiological measurements. This is consistent with previous findings [23].

Prospective recording of bowel motions and incontinent episodes using a paper patient diary is common [25–31]. Paper diaries are believed to be sufficiently accurate [32] and more reliable than memory thereby reducing recall bias [33]. However, a previous study showed that FI patients using paper diaries tend to accumulate data and document it later that day or a successive day, thereby reducing reliability [34]. In this review, the final CS results for incontinent episodes of solid and liquid stool, assessed at completion of treatment, compare well with those reported for the same period in the paper diaries. However, incontinent episodes recorded by patients in their bowel chart for the week prior to first treatment session did not compare well with the initial CS. This may have occurred because: patients were initially uncomfortable completing the bowel chart for incontinent episodes; pre-treatment patients were more focused on reduction in and control of stool frequency and urgency; the CS can reflect a longer period (from daily to more than monthly) compared with the 7-day bowel chart; and some patients at final interview explained that they either failed to complete the bowel

charts accurately or were too embarrassed to fully document the true extent of the problem.

Increased stool frequency has been described as a major problem by patients who have undergone surgery for CRC [35]. The significant reduction in stool frequency using biofeedback in this review confirms previous findings in the general FI population [21, 36, 37] and a case study in this population [38]. Reduced stool frequency allows increased participation in normal daily activities and thus improves quality of life.

The aim of the program is to improve the patients' quality of life. This has generally been measured by either generic or disease-specific quality of life scales. Previous studies of biofeedback in patients with fecal incontinence have demonstrated a holistic/multimodal program achieves the requisite improvement [39–42]. This report confirms that patients having survived the devastating psychological trauma due to cancer diagnosis, surgery and bowel dysfunction were satisfied with the improvement in their bowel function and with the components of the therapy.

The subjective measurement of patient satisfaction with anorectal biofeedback treatment is more widely reported [26, 42–46] and overall satisfaction with bowel function results are consistent with these findings. We have further probed into satisfaction with components of the treatment received, in order to determine where to focus patient care. Further investigation is required on various coping strategies employed in this biofeedback program, particularly the effect of changes in diet, and use of medications and supplements.

In conclusion, these findings confirm that the biofeedback protocol for PSBD in CRC patients is highly successful. Significant improvements were attained for QOL, and symptom severity, number of bowel motions and incontinence were reduced. Given the increased survival statistics for CRC patients, a nationally funded biofeedback treatment program is needed.

Acknowledgments We would like to thank the participants and Stephanie Vuleta, Clinical Scientist, for technical assistance. We acknowledge support of this review from a James Cook University Program Grant. Lynne Bartlett is supported by a scholarship from the Cancer Council, Queensland.

References

1. AIHW (Australian Institute of Health and Welfare), AACR (Australasian Association of Cancer Registries) (2007) Cancer in Australia: an overview, 2006. Cat. No. CAN 32. AIHW, Canberra. (Cancer Series no. 37)
2. Australian Bureau of Statistics (2005) Australian social trends, 2005: colorectal cancer—mortality and morbidity. ABS Catalogue No. 4102.0
3. Prichard PJ, Tjandra JJ (1998) Colorectal cancer. Med J Aust 169:493–498
4. Guillem JG, Cohen AM (1999) Current issues in colorectal cancer surgery. Semin Oncol 26:505–513
5. Temple LK, Bacik J, Savatta SG et al (2005) The development of a validated instrument to evaluate bowel function after sphincter-preserving surgery for rectal cancer. Dis Colon Rectum 48:1353–1365
6. Lundby L, Krogh K, Jensen VJ et al (2005) Long-term anorectal dysfunction after postoperative radiotherapy for rectal cancer. Dis Colon Rectum 48:1343–1349 discussion 1349–1352; author reply 1352
7. Ho YH, Low D, Goh HS (1996) Bowel function survey after segmental colorectal resections. Dis Colon Rectum 39:307–310
8. Camilleri-Brennan J, Steele RJ (1998) Quality of life after treatment for rectal cancer. Br J Surg 85:1036–1043
9. Australian Institute of Health and Welfare (AIHW) (2006) Australian incontinence data analysis and development. AIHW Cat No DIS 44:119
10. Ho YH, Muller R, Veitch C, Rane A, Durrheim D (2005) Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. Aust J Rural Health 13:28–34
11. Nikoletti S, Young J, Levitt M, King M, Chidlow C, Hollingsworth S (2003) Preventing and managing faecal incontinence after sphincter-saving surgery for colorectal cancer. Available at: http://www.bladderbowel.gov.au/ncms/projects/phases/preventandmanage.htm
12. Allgayer H, Dietrich CF, Rohde W, Koch GF, Tuschhoff T (2005) Prospective comparison of short- and long-term effects of pelvic floor exercise/biofeedback training in patients with fecal incontinence after surgery plus irradiation versus surgery alone for colorectal cancer: clinical, functional and endoscopic/endosonographic findings. Scand J Gastroenterol 40:1168–1175
13. Norton C, Kamm MA (2001) Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults—a systematic review. Aliment Pharmacol Ther 15:1147–1154
14. Baeten C, Bartolo DC, Lehur PA et al (2007) Consensus conference on faecal incontinence. Tech Coloproctol 11:225–233
15. Sloots K, Bartlett L (2009) Practical strategies for treating postsurgical bowel dysfunction. J Wound Ostomy Continence Nurs 36(5):522–527
16. Brusciano L, Limongelli P, Del Genio G et al (2007) Useful parameters helping proctologists to identify patients with defaecatory disorders that may be treated with pelvic floor rehabilitation. Tech Coloproctol 11:45–50
17. Jorge JM, Wexner SD (1993) Etiology and management of fecal incontinence. Dis Colon Rectum 36:77–97
18. Rockwood TH, Church JM, Fleshman JW et al (2000) Fecal incontinence quality of life scale: quality of life instrument for patients with fecal incontinence. Dis Colon Rectum 431:9–16 discussion 16–17
19. Rockwood T (2008) The Author Replies. Dis Colon Rectum 51(9):1434
20. Norton C, Chelvanayagam S (2001) Methodology of biofeedback for adults with fecal incontinence: a program of care. J Wound Ostomy Continence Nurs 28:156–168
21. Ho YH, Chiang JM, Tan M, Low JY (1996) Biofeedback therapy for excessive stool frequency and incontinence following anterior resection or total colectomy. Dis Colon Rectum 39:1289–1292
22. Sloots K, Bartlett L, Ho YH (2009) Treatment of postsurgery bowel dysfunction: biofeedback therapy. J Wound Ostomy Continence Nurs 36(6):651–658
23. Baxter NN, Rothenberger DA, Lowry AC (2003) Measuring fecal incontinence. Dis Colon Rectum 46:1591–1605
24. Cheetham MJ, Brazzelli M, Norton CC, Glazener CM (2002) Drug treatment for faecal incontinence in adults. Cochrane Database Syst Rev 3:CD002116

25. Tuteja AK, Rao SS (2004) Review article: recent trends in diagnosis and treatment of faecal incontinence. Aliment Pharmacol Ther 19:829–840
26. Rao SS, Welcher KD, Happel J (1996) Can biofeedback therapy improve anorectal function in fecal incontinence? Am J Gastroenterol 91:2360–2366
27. Naliboff BD (2004) Choosing outcome variables: global assessment and diaries. Gastroenterology 126:S129–S134
28. Enck P (1993) Biofeedback training in disordered defecation. A critical review. Dig Dis Sci 38:1953–1960
29. Loening-Baucke V (1990) Efficacy of biofeedback training in improving faecal incontinence and anorectal physiologic function. Gut 31:1395–1402
30. Whitehead WE, Burgio KL, Engel BT (1985) Biofeedback treatment of fecal incontinence in geriatric patients. J Am Geriatr Soc 33:320–324
31. Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA (2003) Randomized controlled trial of biofeedback for fecal incontinence. Gastroenterology 125:1320–1329
32. Green AS, Rafaeli E, Bolger N, Shrout PE, Reis HT (2006) Paper or plastic? Data equivalence in paper and electronic diaries. Psychol Methods 11:87–105
33. Irvine EJ, Whitehead WE, Chey WD et al (2006) Design of treatment trials for functional gastrointestinal disorders. Gastroenterology 130:1538–1551
34. Stone AA, Shiffman S, Schwartz JE, Broderick JE, Hufford MR (2002) Patient non-compliance with paper diaries. BMJ 324:1193–1194
35. Nikoletti S, Young J, Levitt M, King M, Chidlow C, Hollingsworth S (2008) Bowel problems, self-care practices, and information needs of colorectal cancer survivors at 6 to 24 months after sphincter-saving surgery. Cancer Nurs 31:389–398
36. Ho YH, Tan M (1997) Biofeedback therapy for bowel dysfunction following low anterior resection. Ann Acad Med Singapore 26:299–302
37. Chiarioni G, Bassotti G, Stanganini S, Vantini I, Whitehead WE, Stegagnini S (2002) Sensory retraining is key to biofeedback therapy for formed stool fecal incontinence. Am J Gastroenterol 97:109–117
38. Ho YH (2001) Postanal sphincter repair for anterior resection anal sphincter injuries: report of three cases. Dis Colon Rectum 44:1218–1220
39. Byrne CM, Pager CK, Rex J, Roberts R, Solomon MJ (2002) Assessment of quality of life in the treatment of patients with neuropathic fecal incontinence. Dis Colon Rectum 45:1431–1436
40. Byrne CM, Solomon MJ, Rex J, Young JM, Heggie D, Merlino C (2005) Telephone vs. face-to-face biofeedback for fecal incontinence: comparison of two techniques in 239 patients. Dis Colon Rectum 48:2281–2288
41. Rex J, Heggie D (2003) Anorectal investigation facility biofeedback programme. J Stomal Ther Aust 23(2)
42. Ozturk R, Niazi S, Stessman M, Rao SS (2004) Long-term outcome and objective changes of anorectal function after biofeedback therapy for faecal incontinence. Aliment Pharmacol Ther 20:667–674
43. Davis KJ, Kumar D, Poloniecki J (2004) Adjuvant biofeedback following anal sphincter repair: a randomized study. Aliment Pharmacol Ther 20:539–549
44. Bravo Gutierrez A, Madoff RD, Lowry AC, Parker SC, Buie WD, Baxter NN (2004) Long-term results of anterior sphincteroplasty. Dis Colon Rectum 47:727–731 discussion 731–732
45. Martinez-Puente Mdel C, Pascual-Montero JA, Garcia-Olmo D (2004) Customized biofeedback therapy improves results in fecal incontinence. Int J Colorectal Dis 19:210–214
46. Ryn AK, Morren GL, Hallbook O, Sjodahl R (2000) Long-term results of electromyographic biofeedback training for fecal incontinence. Dis Colon Rectum 43:1262–1266

OSTOMY CARE

Practical Strategies for Treating Postsurgical Bowel Dysfunction

Kathryn Sloots ■ Lynne Bartlett

Postsurgical bowel dysfunction is a potential complication for patients undergoing ileoanal anastomosis, restorative proctocolectomy, and low anterior anastomosis. In our setting, these patients are referred to the Anorectal Physiology Clinic at the Townsville Hospital, Queensland, for comprehensive behavioral therapy. The goals of the therapy are as follows: improve stool consistency, improve control over stool elimination, decrease fecal frequency and rectal urgency, fecal continence without bu`bppfsb obpqof`qflkp lk cll a^ka «rfa fkq^hb) ^ka fk`ob^pb quality of life. This article outlines our holistic approach and pmb`fª`qob^q j bkq pqo^qbdfbp) fk`irafkd ^ppbpp j bkq) bar`^qflk) support and assistance with coping, individualized dietary and «rfa j lafª`^qflkp) j baf`^qflkp) ^ka bubo`fpb÷ ?flcbba_^`h fp rpba ql ebim m^qfbkqp f j molsb ^k^i pmefk`qbo ^ka mbisf` «llo muscle function and bowel elimination habits. Information on the biofeedback component of the treatment program will be described in a subsequent article.

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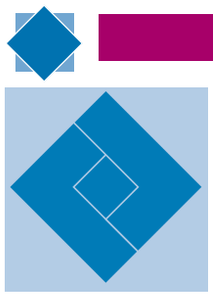

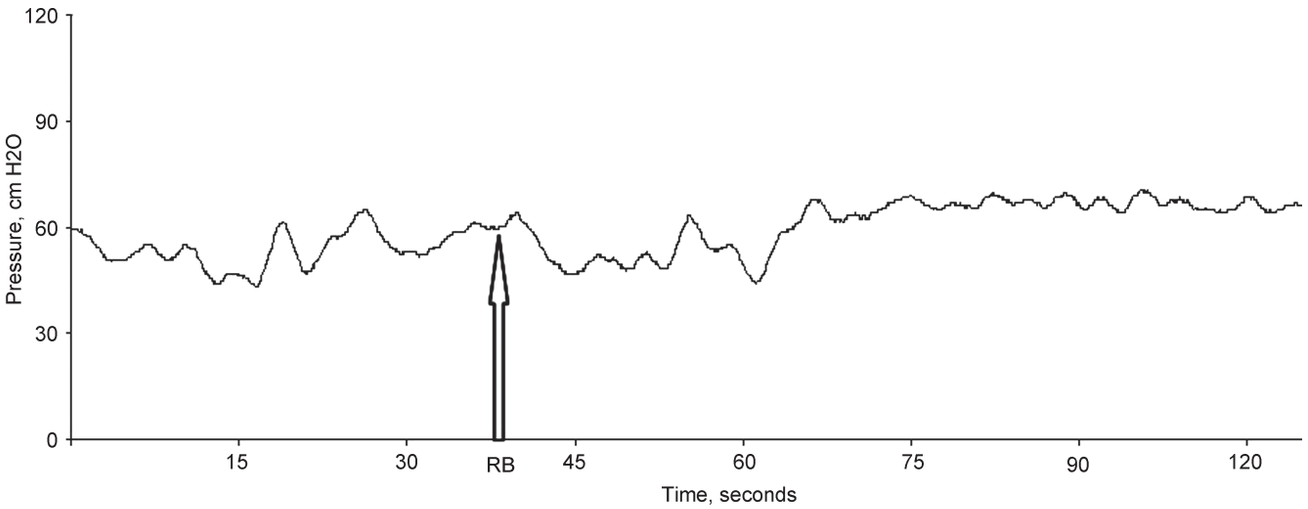
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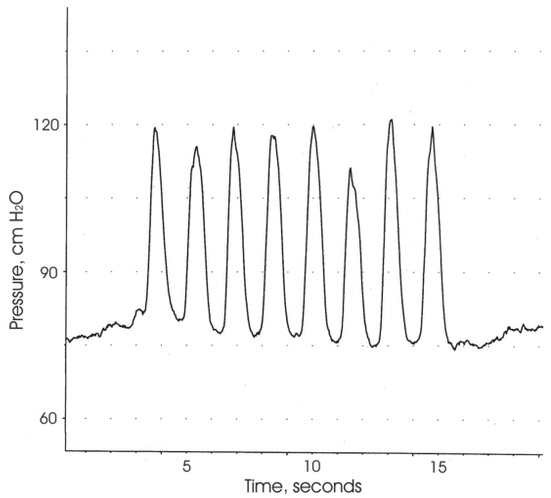
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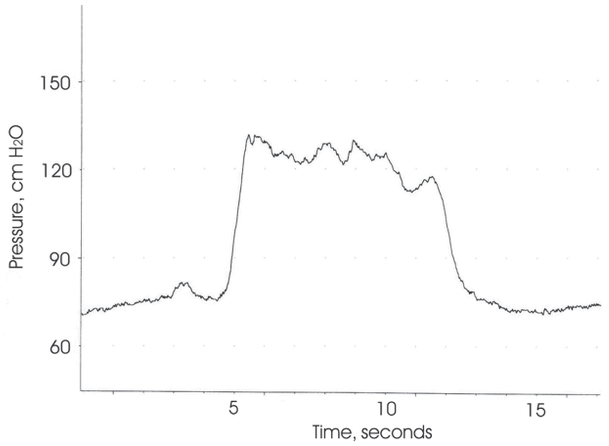

Practice your Exercises

Relax & Breathe

1. Sit, stand or lie with your knees slightly apart. Tighten and pull up the sphincter muscles to about ***half of their maximum*** squeeze. Hold tightened for ……. seconds, and then relax for at least 10 seconds to allow the muscle to recover. Repeat …….times. This will increase the endurance, or staying power, of your muscles.

2. Pull up the muscles as ***quickly and tightly*** as you can, then relax, then pull up ***quickly and tightly*** again, and see how many times you can do this before the muscle gets tired. Start with ……. quick pull-ups.

3. Tighten and pull up the sphincter muscles as ***tightly*** as you can. Hold tightened for …….. seconds, then relax for at least 10 seconds. Repeat …….. times. This will increase the strength of your muscles.

4. Do these exercises …… times every day.

5. As the muscles get stronger you will find that you can hold the squeezes for longer, and that you can do more quick pull-ups without the muscle getting tired.

6. It takes time for exercise to make muscle stronger. You may need to exercise regularly for several months before the muscles gain their full strength. *You need to continue to exercise these muscles for the rest of your life to maintain their strength, and therefore your improvement.*

EXERCISE = IMPROVEMENT = SUCCESS

LIVE THE PROGRAMME

The Correct Sitting Position

1 Elbows on knees **2** Lean forward with straight back **3** Feet on stool

READY
Abdominal bracing
(making your waist wide)

STEADY
Relax and bulge
the tummy muscles

GO
Without straining, relax and widen
the back passage.
Do **NOT** hold your breath.

FINISH
Draw up the back passage firmly

Content has been removed
for privacy reasons

Journal of Clinical Gastroenterology

Supplementary home biofeedback improves quality of life in younger patients with fecal incontinence

--Manuscript Draft--

Manuscript Number:	
Full Title:	Supplementary home biofeedback improves quality of life in younger patients with fecal incontinence
Article Type:	Original Article (Clinical Research)
Keywords:	Biofeedback; fecal incontinence; quality of life; perineometer; randomized clinical trial
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Manuscript Region of Origin:	AUSTRALIA
Abstract:	Background: Biofeedback is a scarce, resource-intensive clinical therapy. It is used to treat patients with bowel problems, including fecal incontinence (FI), who fail to respond to simple dietary advice, medication or pelvic floor exercises. Populations are aging and younger cohorts use technology in managing their health, affording FI self-management opportunities. Aim: To investigate whether supplementary home-based biofeedback improves FI and quality of life (QOL). Methods: 75 incontinent participants (12 male), mean age 61.1 years consented to participate. 39 (5 male) were randomized to the standard biofeedback protocol plus daily home use of a PeritronTM perineometer (intervention) and 36 patients (7 male) to the standard biofeedback protocol (control). On completion of the study each perineometer exercise session was rated for technique by two raters, blinded to patient and order of sessions. Results: With the exception of FI QOL scale Lifestyle improvement (intervention - 9.1% vs controls - 0.3%, P = 0.026) and Embarrassment improvement (intervention - 50.0% vs controls - 18.3%, P = 0.026), supplementary home biofeedback did not result in greater clinical improvement for the intervention group as a whole. However on stratification around the mean age, the continence and QOL of younger people in the intervention group were significantly better than those of their control counterparts. Graphed perineometer sessions demonstrated high compliance and improvement in exercise technique. Perineometers provided reassurance, motivation and an exercise reminder ensuring confidence was achieved quickly.

	Conclusions: Home biofeedback was acceptable and well tolerated by all users. Younger participants significantly benefited from using this technology.

Supplementary home biofeedback improves quality of life in younger patients with fecal incontinence

Short Title: Home biofeedback for FI

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Original Contribution:

Abstract:

Background: Biofeedback is a scarce, resource-intensive clinical therapy. It is used to treat patients with bowel problems, including fecal incontinence (FI), who fail to respond to simple dietary advice, medication or pelvic floor exercises. Populations are aging and younger cohorts use technology in managing their health, affording FI self-management opportunities.

Aim: To investigate whether supplementary home-based biofeedback improves FI and quality of life (QOL).

Methods: 75 incontinent participants (12 male), mean age 61.1 years consented to participate. 39 (5 male) were randomized to the standard biofeedback protocol plus daily home use of a Peritron^{TM} perineometer (intervention) and 36 patients (7 male) to the standard biofeedback protocol (control). On completion of the study each perineometer exercise session was rated for technique by two raters, blinded to patient and order of sessions.

Results: With the exception of FI QOL scale Lifestyle improvement (intervention - 9.1% vs controls - 0.3%, P = 0.026) and Embarrassment improvement (intervention - 50.0% vs controls - 18.3%, P = 0.026), supplementary home biofeedback did not result in greater clinical improvement for the intervention group as a whole. However on stratification around the mean age, the continence and QOL of younger people in the intervention group were significantly better than those of their control counterparts. Graphed perineometer sessions demonstrated high compliance and improvement in exercise technique. Perineometers provided reassurance, motivation and an exercise reminder ensuring confidence was achieved quickly.

Conclusions: Home biofeedback was acceptable and well tolerated by all users. Younger participants significantly benefited from using this technology.

Keywords: Biofeedback, fecal incontinence, quality of life, perineometer, randomized clinical trial

INTRODUCTION:

Up to 15% of community residing adults[1] and 72% of aged care residents[2] have fecal incontinence (FI), the accidental leakage of liquid or solid stool. FI adversely affects quality of life (QOL).[3]

Cost effective FI treatments are a priority[4] especially as age has a significant influence on FI[5], aging populations are at unprecedented levels,[6], and health care services are increasingly required to adopt long-term acute care client-centered chronic disease models.[7] Younger more assertive cohorts (baby boomers [born 1946-1965], generations X [1966-1976], Y [1977-1992] and Z [1992+]) often approach clinicians armed with information sourced from the internet.[8] They are also more likely to insist on treatment, unlike their forbears who often suffer in silence.[8,9]

Conservative management strategies include eliminating or reducing FI risk factors, screening high risk patients, bowel habit training, defecation technique, dietary and fluid intake management, medication, exercises, biofeedback-assisted exercise, electrical stimulation, and environmental management. When conservative therapies fail or are unsuitable, treatment options include sacral nerve stimulation, surgery and stoma.[10,11]

Anorectal biofeedback, a conservative first-line treatment,[12] converts pressure readings from an anal sensor to a display screen for visual feedback, thus raising awareness of physiological processes rarely deemed under conscious control. When combined with a holistic treatment program, significant incontinence and QOL improvements can be achieved.[13] However, one-on-one anorectal biofeedback is a scarce, resource-intensive therapy.

Early recruits in a previous study reported they would benefit from having biofeedback equipment at home. The majority of those subsequently asked (90%) reported they would be

happy to trial a home biofeedback device.[13,14] Home biofeedback, using an anal sensor suitable for both men and women, could aid the biofeedback component of a holistic program. Developed in 1948,[15] perineometers have been used to strengthen the pelvic floor, reduce urinary incontinence and treat patients with myelomeningocele, soiling, constipation and FI.[16-24] The Peritron™ perineometer (Cardio Design Pty. Ltd., Oakleigh 3166, Australia), which measures pressure in centimeters of water, consistently at 75% of true pressure,[25] is reliable,[26-28] commercially available, and widely-used.[29] Since 2007 the inclusion of an internal memory has allowed recording of biofeedback guided exercise sessions at home in private, as well as analysis of uploaded data by clinical staff.

Patients with FI who live in rural and remote locations have reported poorer general health than those residing in regional and urban centers[14] and two years following biofeedback treatment their condition has been shown to regress to pre-treatment levels. Training with a home biofeedback device may provide added confidence, both during treatment, and in the long-term.

This study was designed to assess whether supplementary home-use of a Peritron™ perineometer with an anal sensor was acceptable to patients and resulted in better outcomes (FI and QOL) than standard biofeedback.

METHODS:

Participants: Eighty patients, whose FI had not responded to conservative treatment prescribed by their general practitioner over 6-12 months, were referred to the Townsville Hospital Anorectal clinic for biofeedback between June 2007 and May 2010 following manometric assessment by a colorectal surgeon. Four females were excluded from the study (Fig. 1). Eligible participants (76, 13 male) mean age 61.3 years (95% CI 59.5-63.1), were not pregnant, had no gastrointestinal stoma, terminal or mental illness and gave informed consent. In January 2009, following ethics re-approval, the age criterion was increased from 18-70 to 18-80 due to a shortage of eligible patients. Nineteen participants (5 male) had previously undergone bowel surgery, nine (3 male) for colorectal cancer. Four (1 male) participants reported difficulty with rectal emptying. Of the 60 female patients: 32 previously had endoanal ultrasound (24 with external anal sphincter defects - 7 surgically repaired prior to biofeedback referral); 35 had a history of difficult vaginal delivery (13 had vaginal repair surgery), and 7 underwent vaginal repair surgery without reporting difficult vaginal deliveries. Rural/remote participants (37, 7 male) travelled up to 1269km (median: 248 km, IQR: 136-389) to attend the clinics while 39 (7 male) resided within 35 km of the clinic.

Randomization: Thirty-six patients (7 male) were randomized (unrestricted, computer-generated sequence in opaque envelopes) to the standard clinical biofeedback protocol[13] and 40 (6 male) to receive the same with parallel supplementary home perineometer (Fig. 1). Neither patients nor therapist could be blinded to treatment groups once allocated, however all patients received standard treatment protocols to ensure the same issues were addressed[13].

Ethics: The Townsville Hospital (16/06) and James Cook University (H2390) gave ethical approval. The Australian New Zealand Clinical Trials Registry number is ACTRN12606000070538

Study Procedure (Fig. 1): The study was briefly explained to patients by telephone followed by mailing to willing participants of; information about the standard biofeedback program, the study, bowel chart/food diary for completion in the week prior to the first appointment and an appointment date. Treatment included: 3 weekly outpatient sessions; 4 weeks of home practice; and a final reassessment session. The study was conducted on an additional clinic day, which advantaged participants by reducing their waiting time for treatment.

Prior to the first session the researcher (LB) explained the study and demonstrated the perineometer (Fig. 2). Participants completed consent forms, a self-administered FI questionnaire[3], which included the Fecal Incontinence Quality of Life Scale (FIQL),[30] and the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI).[31]

Biofeedback session 1, with therapist KS, has previously been described.[13] Briefly it included: a medical, surgical and medications history including bowel problems and habits; as well as diet, fiber and fluid intake. Anorectal function and proctometrographic evaluation were assessed using clinic manometric equipment and relaxation (diaphragmatic) breathing was taught.[32] Patients were advised to practice relaxation breathing for 7–10 minutes at least twice/day and complete a bowel chart/food diary for the following week.

KS was advised of patient randomization immediately before the second appointment. Patients completed the FIQL and CCF-FI score with LB and were advised of the randomization outcome. Those randomized to supplementary home biofeedback were provided with the equipment (perineometer, anal sensor and tube, disposable latex sensor covers, appropriate lubricant). In session 2, after reviewing diaries from the previous week, participants were instructed in rapid and sustained anal sphincter and pelvic floor muscle exercises using the clinic computerized biofeedback equipment.[13] Techniques including relaxation breathing, pelvic floor muscle exercises, correct toileting posture, and bowel

training to reduce fecal urgency and frequency, and improve rectal sensitivity, anorectal co-ordination and continence were explained.[33] Patients received individualized instruction sheets to assist with home practice of prescribed exercises.

Perineometer participants were coached to perform and save exercise sessions, practicing until confident. Perineometer sensitivity was customized for each participant so sustained squeezes (half strength) half-filled the screen with bars, and rapid squeezes filled the screen. Participants were asked to record one set of exercises/day using the perineometer; taking a maximum of five minutes depending on their ability. Most participants, in both study arms, started with 3-4 rapid squeezes and 2-3 sustained squeezes lasting 3-4 seconds, practicing 6-10 sets daily, to prevent muscle fatigued (which could exacerbate FI). During treatment the aim was to achieve the maximum exercise regimen (10 rapid squeezes plus 6 x 10 second sustained squeezes for both anal and pelvic floor) practiced 5 times per day. The exercise technique taught in the clinic included counting out loud the number of seconds a squeeze was held to ensure the patient did not use their abdominal muscles, hold their breath or bear down while doing the exercises. The technique was checked again in sessions 3 and 4.

Perineometer home performance data were uploaded, graphed, printed and provided to the therapist and participant during session 3. During session 3 all therapy components were reviewed and adjusted as required. The final treatment component to reduce stool fragmentation and improve evacuation was taught using toileting position, relaxation breathing and evacuation technique.[33] Updated instructions for the 4 weeks of home practice were provided, concerns addressed, and perineometer practice conducted as necessary.

The perineometer save mode was set to capture data every 400 milliseconds providing a total of 54 minutes recorded data, so that the data required uploading after two weeks. Two perineometer participants who lived more than 500km away took two perineometers for home

practice; otherwise LB visited all participants at home to upload data and clear perineometer memories. Data were graphed, printed and provided to participants (with written feedback if necessary).

Perineometer participants returned the equipment immediately prior to the final session so that copies of the previous fortnight's graphed data could be provided to them and the therapist during the session. Anorectal function, exercise regimen, bowel charts/food diary and the 4 week home practice were assessed by the therapist and suggestions given for future improvements. Symptom severity and QOL were reassessed; patient satisfaction with progress was recorded, and semi-structured interviews were conducted by LB.

Statistical Analysis: The sample size of 33 participants per group (alpha = 5%, power = 80%) was calculated from the CCF-FI improvement in a previous study[13] (mean 5.8, SD 4.8) and an anticipated difference of 2.5. As a higher dropout rate was expected in the perineometer group, 40 patients were recruited and 34 patients for the biofeedback only group.

Data were analyzed on an intention-to-treat basis, i.e. participants who were randomized to the intervention group but completed the study as controls were analyzed as intervention participants and non-completers assumed to remain unchanged from their last observation. Numerical data are given as mean value and standard deviation (SD) or median value and interquartile range (IQR), depending on the distribution. Comparisons between characteristics were undertaken using χ^2 tests and χ^2 tests for trend, nonparametric Wilcoxon tests, and *t* tests.

When the study was completed rating tables were constructed for each home exercise session recorded in order to assess exercise compliance, performance and technique. Each of the graphed perineometer exercise sessions was allocated a new random reference number. A

control table linking the patient identification number, the download number and graph order number with the new randomized graph number was created. Graphs were entered into 22 spreadsheets as picture files, in the new random reference number order, with each graph rating table linked to an analysis page for each rater. Both raters were blinded to patient, download number and order of sessions. Rapid and sustained anal and pelvic floor squeezes, between were rated (out of 10) for adherence to prescribed technique[13] by researchers LB and MN (example in Fig. 3). Rests between squeezes were measured in seconds. Ratings were then assessed for consistency and conformity using Kuei Lin's concordance correlation coefficient (ICC).[34] Statistical analyses were conducted using SPSS for Windows, Version 20.0. A significance level of 0.05 was adopted *a priori*.

RESULTS:

Seventy-three participants (39 perineometer) completed all sessions (median duration 6 weeks). Four participants (female) assigned to the perineometer group dropped out of this group due to inability to insert the anal sensor; they continued with the standard therapy (two in Session 2 and two during the following week). One of these women and two female control participants failed to complete the study. Data from one male perineometer participant was not analyzed as he had previously received biofeedback (Fig. 1). Data were analyzed for 75 participants (12 male), mean age 61.1 (95% CI 59.2-62.9) years, FI median duration of 24 (IQR 12-60) months.

There was a trend to greater improvement in continence, QOL (Table 1) and squeeze pressures (Table 2) for the perineometer group. However, this improvement was only statistically significant for the Lifestyle (p = 0.026) and Embarrassment (p = 0.026) FIQL Scales.

When stratified by age, above and below the mean (<61.1 n=35, 17 perineometer and ≥61.1, n=40, 22 perineometer), several improvement measures were higher for the perineometer participants than the control participants in the younger cohort: Intervention versus Control (CCF-FI 7 vs 2, *P*=0.035; FIQL Lifestyle 0.2 vs 0.0005, *P*=0.004; Depression 0.1714 vs 0.0005, *P*=0.015; Embarrassment 0.6667 vs 0.0005, *P*=0.010; and Global 12.8 vs 0.9, *P*=0.010). There was no difference in FIQL Coping scale (*P*=0.137) improvement between the study arms for younger participants. Nor were there any differences for any of the FIQL scales or CCF-FI score between the study arms for participants older than the mean age (all *P* >0.435).

Participants were highly satisfied with the results of treatment (perineometer 9.1/10; control 8.3/10); there were no significant differences between the study arms or younger and older

participants. Improvement in bowel control was similar for both groups (Table 1). There were no adverse events.

The total duration of daily exercises prescribed in Session 2 (rapid plus sustained) was 214 (IQR: 168-254) seconds per day and 254 (IQR: 221-300) seconds in session 3 for the 4 week home practice. There was no difference in prescribed exercise duration between study arms (Session 2: P=0.754; Session 3: *P*=0.599). Perineometer participants reported the exercise instruction and practice component of biofeedback treatment more helpful than control participants (*P*=0.044, Fig. 4).

Perineometer participants (35/39) attempted to record 1439 exercise sessions during treatment with 29/35 recording at least one session every day in week 2, 21/35 recording ≥1 session daily in weeks 3-4 and 15/35 recording ≥1 session daily in weeks 5-6. Compliance (actual/prescribed) was reported as 100% if one or more sessions were performed daily. Overall compliance was excellent with 93% in the first week to 83% for the initial fortnight of home practice and 76% in the last fortnight (Fig. 5).

Perineometer participants recorded significantly more moderate/sustained squeezes of the prescribed duration than required in weeks 2-4 ($p < 0.005$), and significantly more ($P < 0.001$) and prolonged ($P = 0.021$) moderate/sustained squeezes in the final two weeks of home practice. Rapid squeezes were performed as prescribed throughout (Table 3). Compliance with prescribed exercise sessions was not significantly different for those younger or older than the mean age. Approximately 80% of the exercise sessions recorded could be analyzed. This rate did not differ between younger and older perineometer participants, or improve over the course of treatment.

Ratings of the exercise technique correlated well between raters LB and MN (rapid squeezes: ICC = 0.695; sustained squeezes: ICC = 0.781). Patients achieved good ratings for rapid squeeze technique and timing within one week, and continued to improve throughout treatment (p = 0.002, Table 5). The initially mediocre sustained squeeze technique steadily improved ($p < 0.001$). Rests between sustained squeezes were frequently inadequate, risking muscle fatigue, although they improved during the study ($p < 0.001$, Table 5). The prescribed 10 second rests were achieved by: 16/35 participants 25% of the time during week 2; 20/33 participants 40% of the time in weeks 3-4; and 23/33 participants 47% of the time in weeks 5-6.

Total exercise duration per set was greater than prescribed ($p < 0.01$, Table 3) and increased significantly over time ($p < 0.001$, Table 5).

Nine control participants (6 < mean age, 50% rural) reported they were disappointed they did not receive a perineometer and one (72 year old) was initially not disappointed, but later commented she would have liked to take the clinic equipment home. Fifteen were not disappointed (two stated they were just relieved to be treated), while five were pleased they were not randomized to receive a perineometer.

Six perineometer participants found using the device inconvenient citing; privacy concerns, insertion pain because of surgical scar tissue (1, changed to control arm), or psychological inability to insert sensor (1, changed to control arm). Fifteen participants found it mostly convenient to use, however, the need for privacy, potential embarrassment when travelling, forgetting how many exercises they had performed or to save sessions was mentioned. Seventeen participants found it convenient; two were initially not confident, one locked the bedroom door and turned on the television; two mentioned occasionally forgetting to save sessions.

Thirty four participants reported the perineometer helped with their exercises; three did not (2 changed arms, 1 unable to obtain readings on the screen). Reported perineometer benefits included: demonstrated correct performance (10); provided reassurance (10); motivated exercise performance (2); gave positive feedback (6); and was a reminder to perform the exercises (2). Sixteen participants reported being confident performing the exercises without the perineometer within one week, 9 within two weeks, 4 within 3 weeks, 3 by the end of the study while 3 would have preferred to continue with the perineometer feedback. Eight participants had maintenance issues: latex covers tore (3); connecting tubes broke (5); anal sensor material detached (1, Fig 2c); one person washed the entire machine rather than the sensor. Twenty three participants (65.7%) said they would have used the perineometer, if offered, regardless of the study; 12 (34.3%) would not. Seventeen (48.6%) said they would use it long-term if available, 11 (31.4%) would use it but not daily and 7 (20%) would not use it long-term. Only 2/35 participants did not adapt to using the anal sensor; 1/35 reported the benefits of the perineometer did not outweigh the inconvenience and 4/33 felt they would have been confident performing their exercises without the perineometer (of the 5 who said they would have been a little confident, 4 felt the perineometer helped them gain confidence quickly). Seven (20%, 5> mean age) of those who used the perineometer took their anal sensor for use with subsequently purchased Cardio Design PFX machines.

A biofeedback video was considered desirable by 60/68 participants, with a greater percentage of younger (< mean age: 93% [28]) than older (84% [32], p=0.028) participants in favor. Half (18) of the older participants and 30% (7) of the younger suggested it could also be a useful back-up to the intensive clinic sessions.

DISCUSSION:

The major findings of this study were that: the group with the home biofeedback device did significantly better in the lifestyle and embarrassment FIQL scales; younger perineometer participants' continence and global FIQL scales were significantly better than similar aged controls; and compliance with prescribed exercises for the perineometer group was excellent and yielded significant improvement in technique and performance over the course of the treatment. Most perineometer participants found the device helped with the exercise program, providing feedback, reassurance, motivation, building confidence quickly and acting as an exercise reminder.

Patient acceptability, satisfaction and impact on QOL of earlier studies of home biofeedback are not well described. One large study (four arms) compared clinic biofeedback treatment plus anal sphincter exercises with the same treatment plus home biofeedback trainers; the authors found the home biofeedback group rated the least improvement of all groups despite receiving the most intensive input compared with the biofeedback group, or the standard treatment groups without biofeedback (with/without sphincter exercises).[24] They concluded that advice and the patient-therapist relationship common to all groups were the primary reasons for improvement rather than the technical aspects of biofeedback. While the patient/therapist relationship in this study was also an important component of treatment, the technical aspects were rated highly (Fig. 4) by both intervention and control participants.

Younger participants in the control group improved least. Disappointment at not receiving a perineometer did not appear related to this lower level of improvement as the results achieved by both younger (6) and older participants (3) who would have liked to use a perineometer were no worse than their corresponding control cohort.

Few participants (3 [3.9%], 1 perineometer) failed to complete this study compared with earlier studies (9.4%-24.3%).[18,19,23,24]. Overall compliance was excellent and even though it dropped over the course of the study from 93% in the first week to 76% in the last fortnight, participants' exercise technique and duration improved over time. Unlike an anal electrical stimulation study (78% completion)[35] where participants were required to use the devices for 20-40 minutes daily and were unaware their compliance was being assessed, our participants actively saved their sessions for later graphing and printing. This knowledge may have improved compliance. While participants were required to use the perineometer for only one of 5-7 sessions daily (≤5 minutes) the need for privacy was considered a concern by about half the participants (18/35). Thus privacy and scheduling 20-40 minutes daily may be reasons for poor compliance in the stimulation study.[35]

Whether a self-managed conservative program can improve FI without a one-on-one patient/therapist relationship is debatable. Younger more technically astute generations may favor the anonymity, economics and time savings of such a program.[8] Most participants in this and a previous study[13] suggested a biofeedback video would be a beneficial addition to their clinic treatment. Such a video (including perineometer component) could also be used by physiotherapists, general practitioners or their practice nurses to supplement their routine practice or add a new element to their treatment protocol.

Five control participants were pleased not to receive a perineometer and another 15 were not disappointed to be in this group. Thus a stand-alone self-help home biofeedback program for less severe FI would need to allay patient concerns and demonstrate its efficacy. Anorectal biofeedback is often quoted as successfully improving 50%-80% of FI patients,[12,36,37] while the most recent Cochrane Review of biofeedback and/or sphincter exercises for the treatment of FI reports "there is some evidence from randomized controlled trials to support the

effectiveness of biofeedback therapy for the management of people with fecal incontinence".[38]

Provision of commonly employed components (excepting rectal discrimination training) in a video together with a basic perineometer e.g. PFX Pelvic floor exerciser (with anal sensor costing less than $160) could enable self-managed treatment for less severe cases of FI, supporting the concept of self-management of chronic diseases[7] which would reduce treatment waiting time and demand on therapist resources. A telemedicine biofeedback program with video support and perineometers for rural and remote FI patients should also be explored given the success of a telemedicine trial of urinary incontinence management.[39] The high level of compliance, improvements achieved (younger participants) and feedback from those randomly assigned a perineometer suggests developing such a program is warranted.

The utility of anorectal manometry in routine clinical assessment of patients with defecation disorders has been questioned.[40] There were no significant differences in anorectal manometry readings between study arms in either this study (Table 2) or the previous biofeedback trial by the same authors[13] although incremental squeeze pressures of all participants improved. Omission of anorectal manometry may be economically rational and marginally reduce patient contact time.

Anal manometry enables the therapist to determine: anal sphincter functional length and regularity of internal anal sphincter pressure waves, particularly for patients with post-surgical bowel dysfunction;[32,33] and maximum voluntary contraction squeeze pressure and duration, which provide a guide when prescribing the initial exercise regimen. Proctometography assesses rectal sensitivity (intra-rectal volume required to produce an initial sensation, the first urge to evacuate and the maximum tolerated volume) and the rectosphincteric inhibitory reflex to identify patients who are likely to benefit from rectal

sensitivity modification and urgency training aspects of the program. These results help the patient understand their symptoms and the therapist to target the treatment program to address specific symptoms and treatment goals. Reassessing these measures not only provides feedback to the referring physician, but also provides incentives to the patient to complete treatment.

Limitations of this study included the size of the perineometer memory, clinic access and extended leave (54 weeks) of the therapist. Measuring/rating rapid squeezes (prescribed at one second duration) required at least two readings per second, which provided a maximum of 54 minutes recording time. Thus data needed to be uploaded after the first two weeks of the 4 week home practice session. Hence extra researcher contact was necessary, which had the potential to affect the improvement in the QOL of these study participants. The anorectal biofeedback clinic normally functioned one day per week with one therapist (KS) treating patients referred with FI, chronic pelvic pain or constipation. An additional clinic day per week was added for this study (maximum of 4 patients/sessions per day) with the standard clinic protocol being maintained. The length of the standard treatment protocol (6 weeks) is not long enough to build maximum muscle strength, however given the limited resources available, it provides patients with sufficient skills to continue practicing at home to further strengthen muscles. A back-up video of standard components could add further support.

Conclusions: To the authors' knowledge this is the first study to objectively measure the compliance of FI patients with prescribed home exercises and their improvement in technique over time. Home use of a relatively inexpensive commercially available perineometer with an anal sensor was acceptable and well tolerated by participants, particularly younger patients. With demand for FI management likely to grow, a video treatment program incorporating existing biofeedback therapy components and perineometer use warrants further research.

Such a program would be particularly useful for people unable to attend large central clinics due to distance or ill health.

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References

1 Macmillan AK, Merrie AE, Marshall RJ, Parry BR. The prevalence of fecal incontinence in community-dwelling adults: a systematic review of the literature. *Dis Colon Rectum.* 2004;47:1341-1349.

2 Australian Institute of Health and Welfare (AIHW). Australian incontinence data analysis and development. *AIHW cat no. DIS 44.* 2006;119.

3 Ho YH, Muller R, Veitch C, Rane A, Durrheim D. Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a hospital-based outpatient study. *Aust J Rural Health.* 2005;13:28-34.

4 Pearson J FP, Tucker I, Bolt J, Kelly S, Eastwood S, Wilson S, Kong J, (2002). Incidence of Incontinence as a Factor in Admission to Aged Care Homes: Report prepared for DoHA, Canberra.

5 Pretlove SJ, Radley S, Toozs-Hobson PM, Thompson PJ, Coomarasamy A, Khan KS. Prevalence of anal incontinence according to age and gender: a systematic review and meta-regression analysis. *Int Urogynecol J Pelvic Floor Dysfunct.* 2006;17:407-417.

6 United Nations, *World Population Ageing: 1950-2050*. New York N.Y. ; 2002

7 Victorian Government, edited by Health, Do (Victoria, Australia, 2013).

8 Berkowitz EN, Schewe CD. Generational cohorts hold the key to understanding patients and health care providers: coming-of-age experiences influence health care behaviors for a lifetime. *Health Mark Q.* 2011;28:190-204.

9 Johanson JF, Lafferty J. Epidemiology of fecal incontinence: the silent affliction. *Am J Gastroenterol.* 1996;91:33-36.

10 Norton C. Faecal Incontinence. In: Haslam, JL, J., eds. *Therapeutic Management of Incontinence and Pelvic Pain: Pelvic Organ Disorders.* 2. Milan: Springer; 2007: 199-211.

11 Makol A, Grover M, Whitehead WE. Fecal incontinence in women: causes and treatment. *Womens Health (Lond Engl).* 2008;4:517-528.

12 Norton C, Kamm MA. Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults--a systematic review. *Aliment Pharmacol Ther.* 2001;15:1147-1154.

13 Bartlett L, Sloots K, Nowak M, Ho Y-H. Biofeedback for faecal incontinence: a randomized control study comparing exercise regimen. *Dis Colon Rectum.* 2011;54:846-856.

14 Bartlett LM, Sloots K, Nowak M, Ho YH. Biofeedback therapy for faecal incontinence: a rural and regional perspective. *Rural Remote Health.* 2011;11:1630.

15 Kegel AH. Progressive resistance exercise in the functional restoration of the perineal muscles. *Am J Obstet Gynecol.* 1948;56:238-248.

16 Loening-Baucke V, Desch L, Wolraich M. Biofeedback training for patients with myelomeningocele and fecal incontinence. *Dev Med Child Neurol.* 1988;30:781-790.

17 Loening-Baucke V. Biofeedback therapy for fecal incontinence. *Dig Dis.* 1990;8:112-124.

18 Patankar SK, Ferrara A, Levy JR, Larach SW, Williamson PR, Perozo SE. Biofeedback in colorectal practice: a multicenter, statewide, three-year experience. *Dis Colon Rectum.* 1997;40:827-831.

19 Perozo S, Ferrara A, Patankar S, Larach S, Williamson P. Biofeedback with home trainer programme is effective for both incontinence and pelvic floor dysfunction. *Tech Coloproctol.* 1997;5:6-9.

20 Musial F, Hinninghofen H, Frieling T, Enck P. [Therapy of fecal incontinence in elderly patients: Study of a home biofeedback training program]. *Z Gerontol Geriatr.* 2000;33:447-453.

21 Griffiths P, Dunn S, Evans A, Smith D, Bradnam M. Portable biofeedback apparatus for treatment of anal sphincter dystonia in childhood soiling and constipation. *J Med Eng Technol.* 1999;23:96-101.

22 Heymen S, Wexner SD, Vickers D, Nogueras JJ, Weiss EG, Pikarsky AJ. Prospective, randomized trial comparing four biofeedback techniques for patients with constipation. *Dis Colon Rectum.* 1999;42:1388-1393.

23 Heymen S, Pikarsky AJ, Weiss EG, Vickers D, Nogueras JJ, Wexner SD. A prospective randomized trial comparing four biofeedback techniques for patients with faecal incontinence. *Colorectal Dis.* 2000;2:88-92.

24 Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence. *Gastroenterology.* 2003;125:1320-1329.

25 Simpson RR, Kennedy ML, Nguyen MH, Dinning PG, Lubowski DZ. Anal Manometry: A Comparison of Techniques. *Dis Colon Rectum.* 2006;1033-1038.

26 Rahmani N, Mohseni-Bandpei MA. Application of perineometer in the assessment of pelvic floor muscle strength and endurance: a reliability study. *J Bodyw Mov Ther.* 2011;15:209-214.

27 Frawley HC, Galea MP, Phillips BA, Sherburn M, Bo K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourol Urodyn.* 2006;25:236-242.

28 Hundley AF, Wu JM, Visco AG. A comparison of perineometer to brink score for assessment of pelvic floor muscle strength. *Am J Obstet Gynecol.* 2005;192:1583-1591.

29 Barbosa P, Franco M, Souza FO, Antônio F, Montezuma T, Ferreira C. Comparison between measurements obtained with three different perineometers. *Clinics (São Paulo, Brazil).* 2009;64:527-533.

30 Rockwood TH, Church JM, Fleshman JW et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum.* 2000;43:9-16.

31 Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum.* 1993;36:77-97.

32 Bartlett L, Sloots K, Nowak M, Ho Y-H. Impact of relaxation breathing on the internal anal sphincter in patients with fecal incontinence. *Australian and New Zealand Continence Journal (ANZCJ).* 2012;18:38-45.

33 Sloots K, Bartlett L, Ho YH. Treatment of postsurgery bowel dysfunction: biofeedback therapy. *J Wound Ostomy Continence Nurs.* 2009;36:651-658.

34 Muller R, Buttner P. A critical discussion of intraclass correlation coefficients. *Stat Med.* 1994;13:2465-2476.

35 Norton C, Gibbs A, Kamm MA. Randomized, controlled trial of anal electrical stimulation for fecal incontinence. *Dis Colon Rectum.* 2006;49:190-196.

36 Norton C, Whitehead WE, Bliss DZ, Harari D, Lang J. Management of fecal incontinence in adults. *Neurourol Urodyn.* 2010;29:199-206.

37 Heymen S, Jones KR, Ringel Y, Scarlett Y, Whitehead WE. Biofeedback treatment of fecal incontinence: a critical review. *Dis Colon Rectum.* 2001;44:728-736.

38 Norton C, Cody JD. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *The Cochrane Database of Systematic Reviews.* 2012;7:CD002111.

39 Hui E, Lee PS, Woo J. Management of urinary incontinence in older women using videoconferencing versus conventional management: a randomized controlled trial. *J Telemed Telecare.* 2006;12:343-347.

40 Raza N, Bielefeldt K. Discriminative value of anorectal manometry in clinical practice. *Dig Dis Sci.* 2009;54:2503-2511.

Figure 1: Progress of participants through study (CONSORT diagram)

Figure 2: Peritron^{TM} Perineometer (displaying baseline 1 of 8 bars), tube and anal sensors *(a) anal sensor as provided; (b) anal sensor with latex cover; (c) anal sensor with material inadvertently detached*

Figure 3: Rated perineometer session of rapid and sustained anal sphincter and pelvic floor muscle squeezes

Figure 4: Patients' assessment of helpfulness of treatment components

Figure 5: Perineometer exercise sessions for 35 participants (4/39 participants could not use device)

Table 1: Continence, Quality of Life changes compared by intervention

	Intervention	Pre-therapy Median (IQR)	Post-therapy Median (IQR)	Improvement/ Change Median Score	Improvement/ Change % [1]	*P* value
Continence Grading Scale [2]						
Total Score (Max 20)	Perineometer	15.0 (10.0-17.0)	6.0 (3.8- 9.0)	7.000	52.9%	0.135 [4]
	Control	12.0 (10.0-16.0)	5.0 (3.0-12.3)	5.500	50.0%	
	All	14.0 (10.0-16.0)	6.0 (4.0-11.0)	6.000		**<0.001** [5]
FI Quality of Life Subscales [3]						
Lifestyle	Perineometer	3.3 (2.3- 3.7)	3.7 (3.1- 3.9)	0.300	9.1%	**0.026** [4]
	Control	3.3 (2.4- 3.7)	3.7 (2.6- 3.9)	0.056	0.3%	
	All	3.3 (2.3- 3.7)	3.7 (3.0- 3.9)	0.200		**<0.001** [5]
Coping	Perineometer	1.9 (1.3- 2.7)	3.0 (2.4- 3.4)	0.889	46.2%	0.093 [4]
	Control	1.9 (1.3- 3.1)	2.9 (1.9- 3.7)	0.556	19.3%	
	All	1.9 (1.3- 3.0)	3.0 (2.3- 3.5)	0.639		**<0.001** [5]
Depression	Perineometer	2.9 (2.1- 3.4)	3.5 (3.0- 3.8)	0.286	14.7%	0.102 [4]
	Control	3.0 (2.0- 3.5)	3.3 (2.1- 3.8)	0.143	6.7%	
	All	3.0 (2.1- 3.4)	3.4 (2.5- 3.8)	0.229		**<0.001** [5]
Embarrassment	Perineometer	2.0 (1.3- 3.3)	3.0 (2.3- 3.7)	1.000	50.0%	**0.026** [4]
	Control	2.0 (1.7- 2.7)	2.7 (2.0- 4.0)	0.500	18.3%	
	All	2.0 (1.3- 2.3)	3.0 (2.0- 3.7)	0.667		**<0.001** [5]
Weekly Bowel Chart [6]						
Incontinent episodes	Perineometer	3.5 (2.0- 7.0)	1.0 (0.0- 3.0)	2.000	64.1%	0.189 [4]
	Control	4.0 (2.0- 7.0)	1.0 (0.0- 5.0)	1.000	64.4%	
	All	4.0 (2.0- 7.0)	1.0 (0.0- 3.3)	2.000		**<0.001** [5]
Bowel motions	Perineometer	11.0 (7.0-19.0)	10.0 (7.0-17.0)	-1.000	9.1%	0.965 [4]
	Control	10.0 (7.0-16.0)	7.0 (6.0-12.5)	-1.000	12.5%	
	All	11.0 (7.0-16.0)	8.5 (7.0-14.0)	-1.000		**0.024** [5]
Final interview [7]						
Bowel control rating (1-10)	Perineometer	3.0 (1.5-4.0)	7.5 (6.0-8.3)	4.000	59.1%	0.537 [4]
	Control	2.5 (1.0-3.6)	6.8 (5.0-8.0)	4.000	62.5%	
	All	2.5 (1.0-4.0)	7.0 (6.0-8.0)	4.000		**<0.001** [5]

Number of patients = 75: Peritron=39, Control=36; IQR= inter-quartile range
1: Improvement on baseline
2: Cleveland Clinic Florida Fecal Incontinence Score
3: Fecal Incontinence Quality of Life Scale, Rockwood et al 2000; scales calculated as per Rockwood 2008
4: p value comparing changes between study arms pre/post therapy was measured using the Wilcoxon Unpaired test
5. p value comparing pre/post therapy using Wilcoxon Paired signed ranks test
6. Bowel charts completed in the week prior to first and last appointment
7. Bowel rating (Pre/Post treatment) asked at final interview (n=72 Peritron=38, Control=34)

Table 2: Anorectal manometry compared by intervention (ITT)

Anorectal Physiology	Intervention	Pre-therapy Median (IQR)	Post-therapy Median (IQR)	*P* value
Mean resting pressure (mmHg)	Peritron	31 (24-51)	34 (20-52)	0.384[1]
	Control	38 (23-57)	39 (24-53)	
	All	34 (24-53)	38 (22-52)	0.988[2]
Maximum Squeeze pressure (mmHg)	Peritron	55 (39-86)	72 (47-104)	0.935[1]
	Control	53 (37-82)	61 (37-109)	
	All	54 (38-85)	65 (41-105)	**0.007**[2]
Volume of initial rectal sensation (ml)	Peritron	21 (18-25)	23 (18-29)	0.506[1]
	Control	22 (18-37)	23 (18-34)	
	All	22 (18-32)	23 (18-30)	0.609[2]
Volume at first urge (ml)	Peritron	60 (45-90)	80 (50-95)	0.606[1]
	Control	65 (46-95)	75 (55-87)	
	All	60 (45-90)	80 (55-90)	0.751[2]
Maximum tolerable volume (ml)	Peritron	155 (107-200)	145 (110-180)	0.489[1]
	Control	155 (116-179)	140 (108-171)	
	All	155 (110-195)	140 (110-175)	0.088[2]

Number of patients = 75: Peritron=39, Control=36; IQR= inter-quartile range

1: Intervention changes pre/post therapy compared using the Wilcoxon Unpaired test

2. Pre/post therapy manometry compared using Wilcoxon Paired signed ranks test

Table 3: Exercises prescribed and performed by Perineometer participants

		Rapid squeezes[1] (#)	Moderate/sustained squeezes[1] (#)	(Duration)	Total seconds of exercise per set[2]
Week 2	Prescribed	10 (8-12)	6 (6-6)	3.5 (3-5)	30 (23-42)
	Performed	9 (7-11)	7 (5-9)	4 (3-6)	45 (29-62)
	P[3]	0.085	**0.005**	0.088	**0.008**
Week 3-6	Prescribed	14 (10-18)	6 (6-7)	5 (4-7)	48 (37-60)
Week 3-4	Performed	14 (9-19)	8 (7-10)	6 (4-8)	69 (48-96)
	P[3]	0.688	**<0.001**	0.069	**<0.001**
Week 5-6	Performed	14 (10-20)	9 (7-13)	7 (4-9)	77 (58-109)
	P[3]	0.394	**<0.001**	**0.021**	**<0.001**

N=35, 1085 sessions rated from 1439 sessions recorded

[1] Median (interquartile range) number and duration of anal (50%) and pelvic floor (50%) squeezes

[2] Sets of exercises per day prescribed in week 2 = 6.5(IQR:6-6.5); sets prescribed in weeks 3-6 = 5(IQR:5-6.5; 1 set required to be performed using the Perineometer each day

[3] Wilcoxon Unpaired test provided *P* value in comparing prescribed and performed exercises

Table 4: Exercise technique improvement of exercises performed and recorded with Perineometer[1]

Median rating[2] / 10	Week			Improvement P		
	2	3+4	5+6	2→3+4	3→4/5+6	2→5+6
Overall rating	6.4	7.4	7.4	**<0.001**	**0.027**	**<0.001**
Rapid Squeeze technique rating	8.3	9.0	9.2	**0.003**	0.129	**0.002**
Rapid rest rating	7.8	8.8	9.0	**0.004**	0.732	0.098
Sustained Squeeze technique rating	5.3	6.5	6.9	**<0.001**	0.175	**<0.001**
Rest duration between sustained squeezes (seconds)	3.5	6.5	7.1	**<0.001**	0.079	**<0.001**
Recorded daily exercise (seconds)	45	69	77	**<0.001**	**0.014**	**<0.001**

N=35, 1085 sessions rated from 1439 sessions recorded

1: Peritron™ Perineometer (Cardio Design Pty. Ltd., Oakleigh 3166, Australia)

2: Ratings for squeeze technique averaged between rater; rest ratings based on time (same for both raters)

Figure
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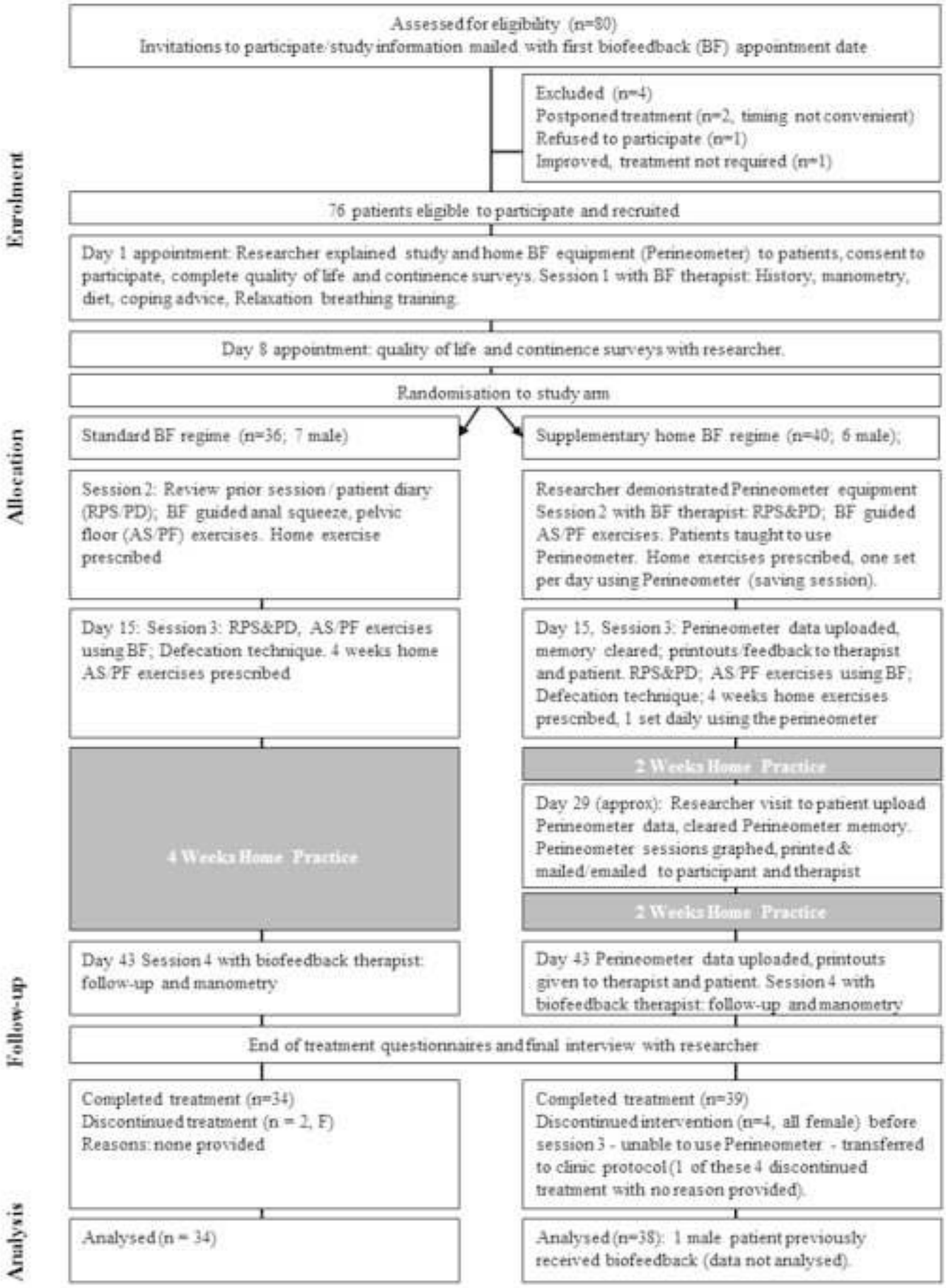

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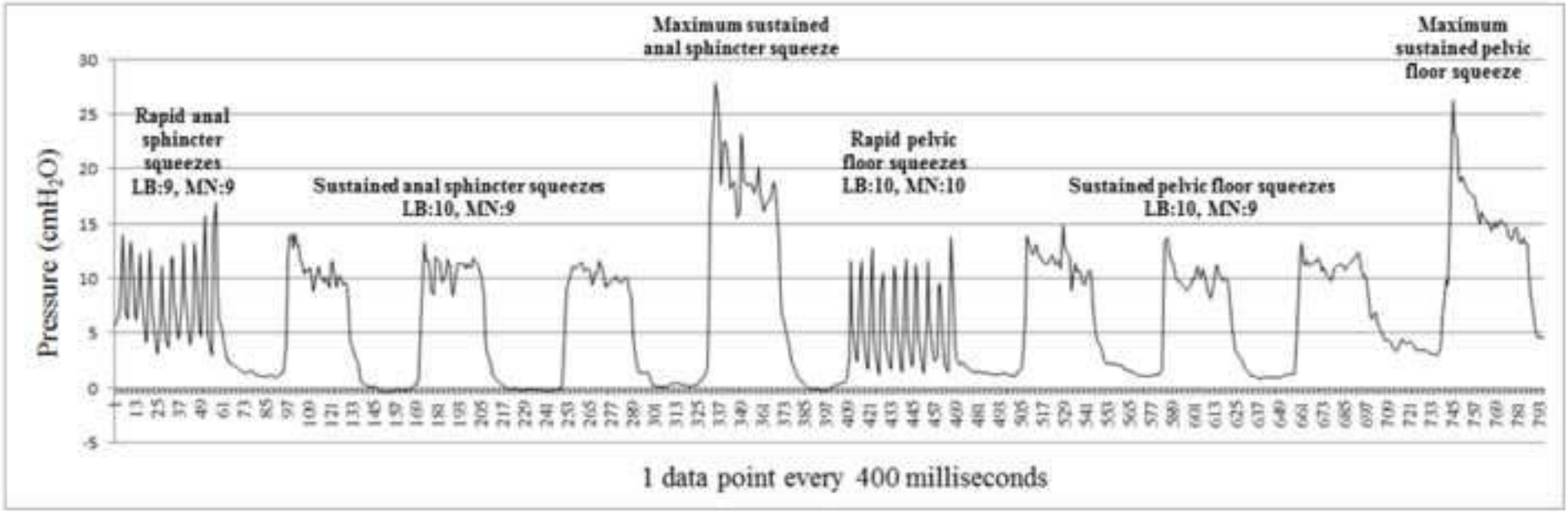

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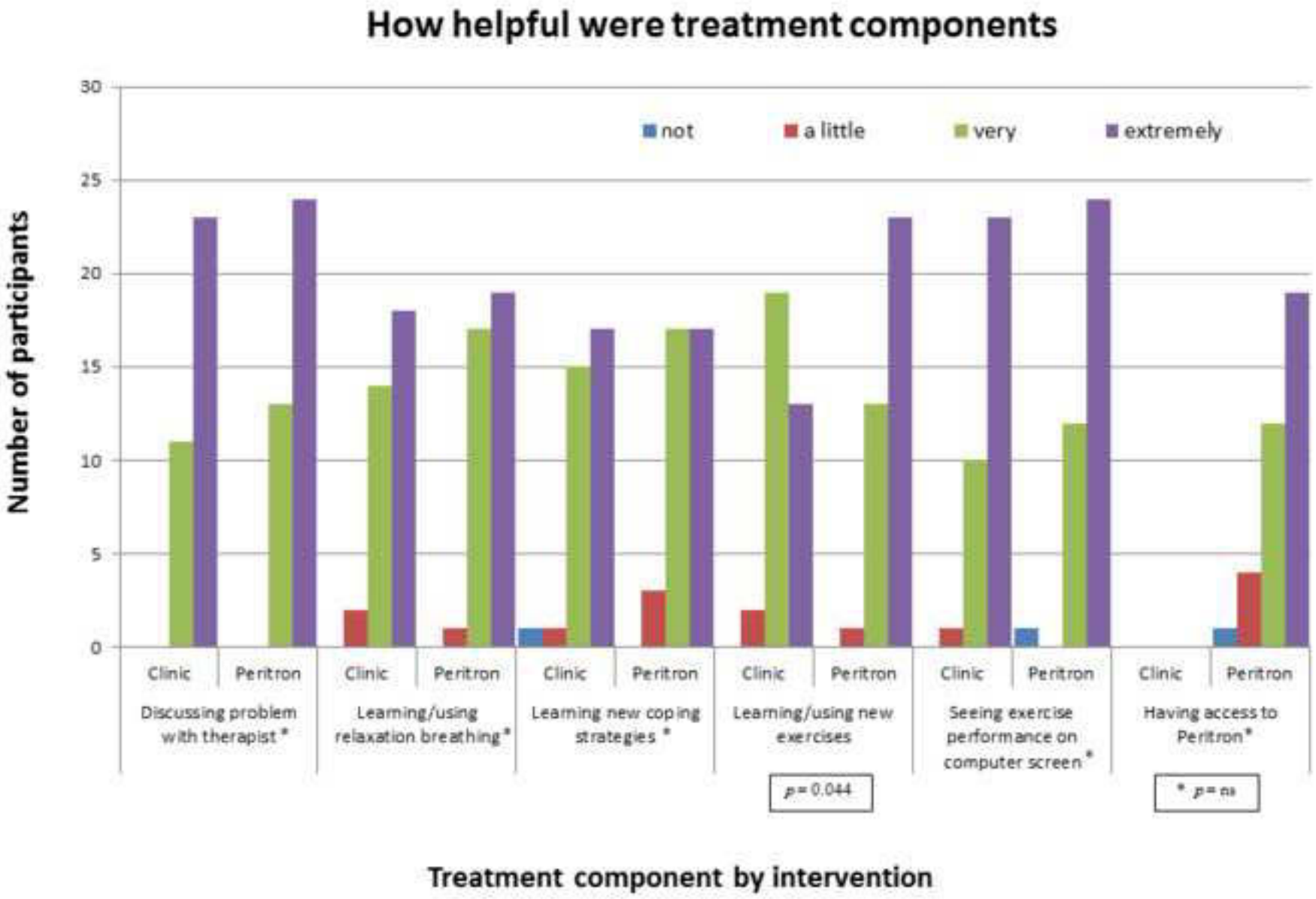

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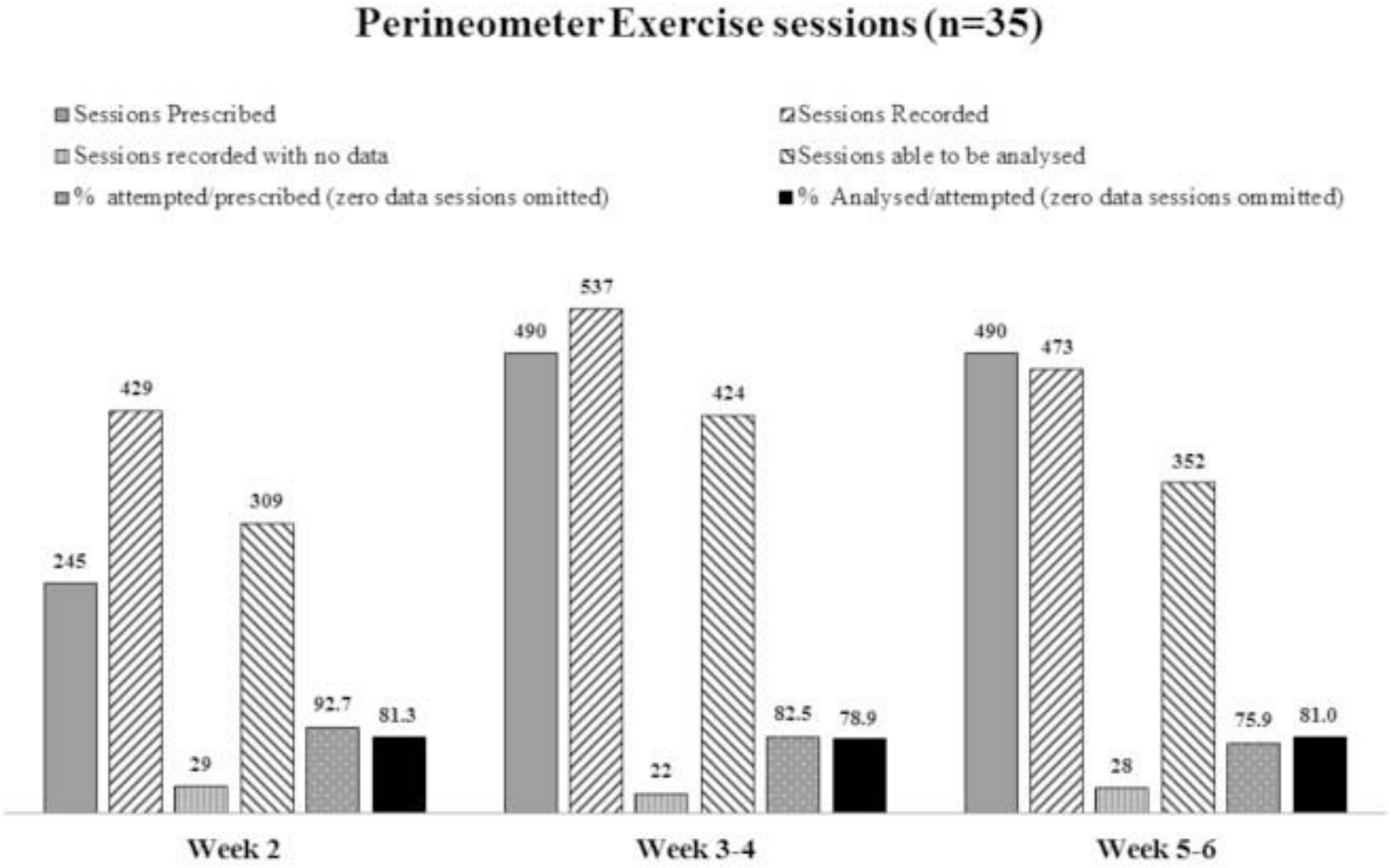

% Compliance: One or more sessions per day = 1; 7 (14) or more per week (fortnight) = 100%

*Cover Letter

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Wednesday, 30 October 2013

Dear Editor-in-Chief,

We wish to submit the attached manuscript:

Supplementary home biofeedback improves quality of life in younger patients with fecal incontinence by Lynne Bartlett, Kathryn Sloots, Madeleine Nowak and Yik-Hong Ho to be considered for publication in Journal of Clinical Gastroenterology.

The major findings of this study were that continence and QOL improvement was greater in the perineometer group. Compliance was excellent and significant improvement in exercise technique and performance was seen over the course of the treatment. Rests between sustained squeezes were frequently inadequate, risking muscle fatigue. Most perineometer participants found they helped with the exercise program, providing feedback, reassurance, motivation, building confidence quickly and acting as an exercise reminder.

All authors have contributed to the work and agreed on a final version. The manuscript is not being considered by any other journal.

Yours sincerely,

Lynne Bartlett
DrPH Candidate

Anton Breinl Centre for Public Health and Tropical Medicine

CHAPTER 6: RELAXATION BREATHING

Concern about incontinent episodes, especially in public, can contribute to stress, anxiety , depression, isolation and reduced quality of life among people with faecal incontinence. In patients with post-surgery bowel dysfunction, loose stools, frequent defecation, and incontinence may result in heightened sensitivity to the presence of stool in the lower bowel or reservoir, also provoking anxiety or panic (Chapter 5.3). Shallow or rapid breathing due to anxiety, panic or fear reflects the "fight or flight" activity of the autonomic nervous system. In contrast relaxation (diaphragmatic) breathing elicits a relaxation response [1] and has been successfully used as a therapy in the treatment of stress, panic disorder, and diarrhoea-predominant irritable bowel syndrome [1-3]. Relaxation breathing is a component of a number of biofeedback programs for disordered defecation [4-6] including the Townsville Hospital anorectal biofeedback program (Chapter 5).

Study aim:

- *To investigate the effect of relaxation breathing on anorectal function*

Publication arising from this chapter

6.1 Impact of relaxation breathing on the internal anal sphincter

Bartlett L, Sloots K, Nowak M, Ho Y-H. Impact of relaxation breathing on the internal anal sphincter in patients with fecal incontinence. The Australian and New Zealand Continence Journal. 2012;18:38-45

My estimated contribution was 81% (Contributors table, page xv)

References

1. Dusek JA, Benson H , Mind-body medicine: a model of the comparative clinical impact of the acute stress and relaxation responses. *Minnesota Medicine*, 2009. 92(5): 47-50.

2. Penava SJ, Otto MW, Maki KM, Pollack MH, Rate of improvement during cognitive-behavioral group treatment for panic disorder. *Behaviour Research and Therapy*, 1998. 36(7-8): 665-73.

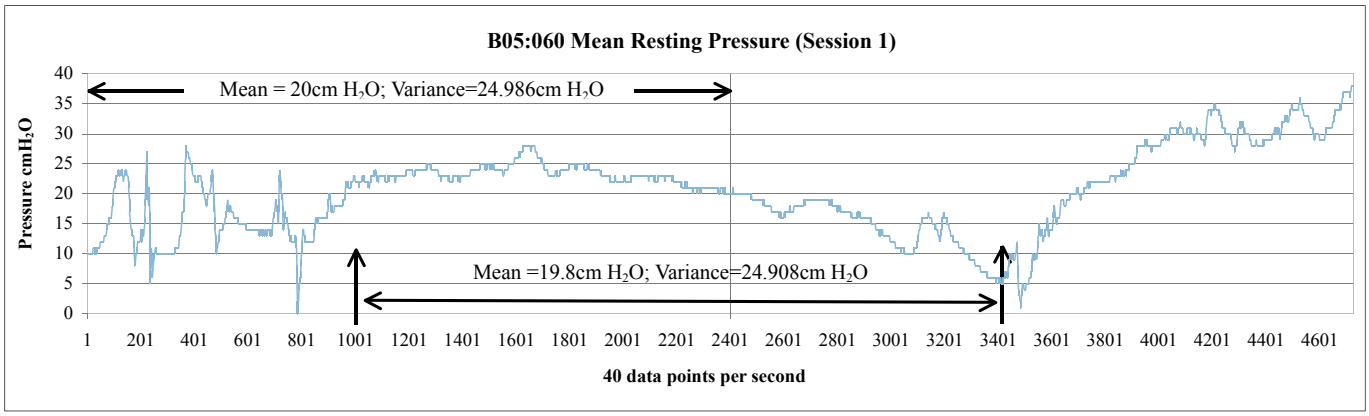
3. Taneja I, Deepak KK, Poojary G, Acharya IN, Pandey RM, Sharma MP, Yogic versus conventional treatment in diarrhea-predominant irritable bowel syndrome: a

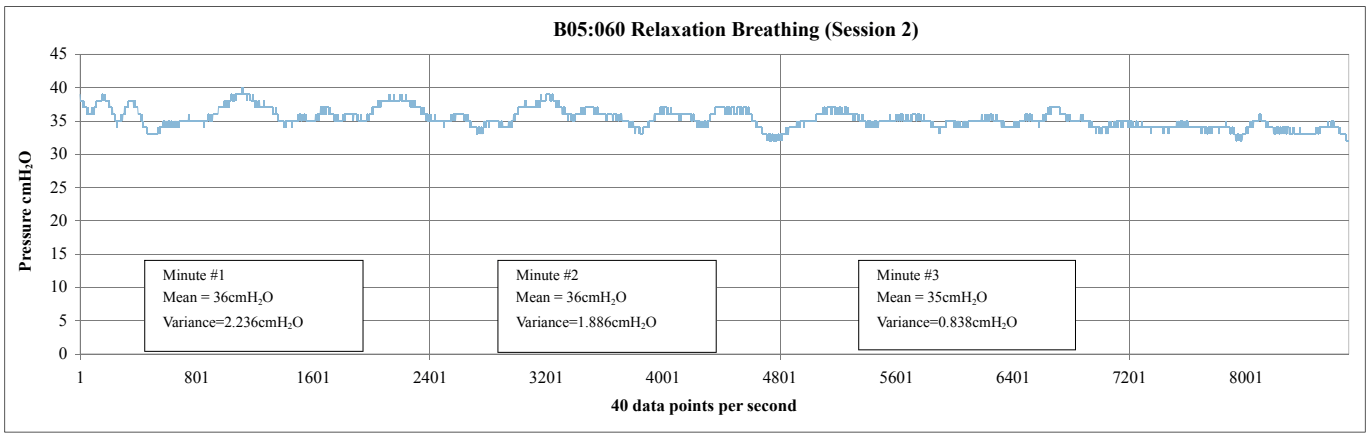
randomized control study. *Applied Psychophysiology and Biofeedback*, 2004. 29(1): 19-33.

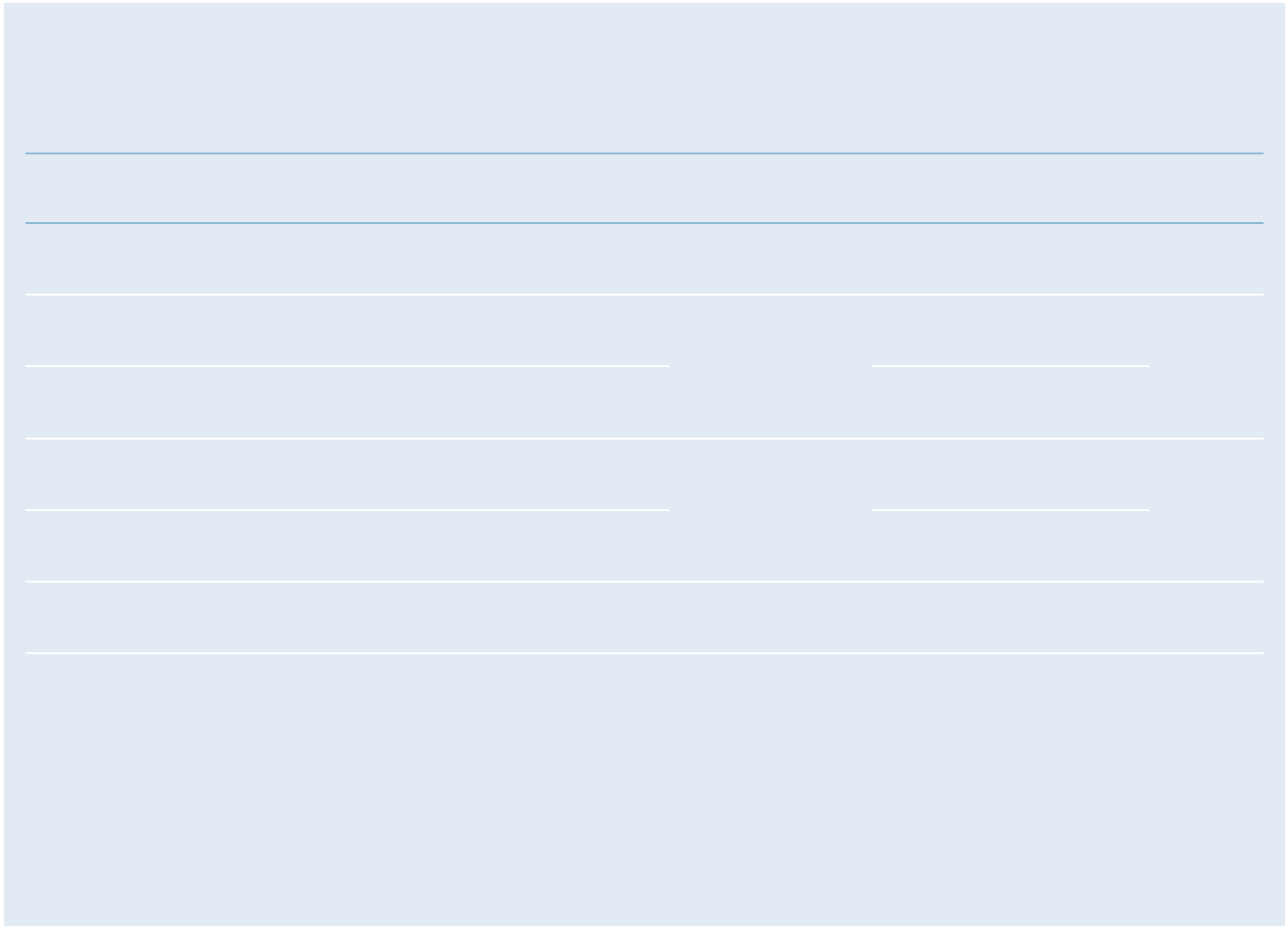
4. Rao SS, Constipation: evaluation and treatment. *Gastroenterology Clinics of North America*, 2003. 32(2): 659-83.

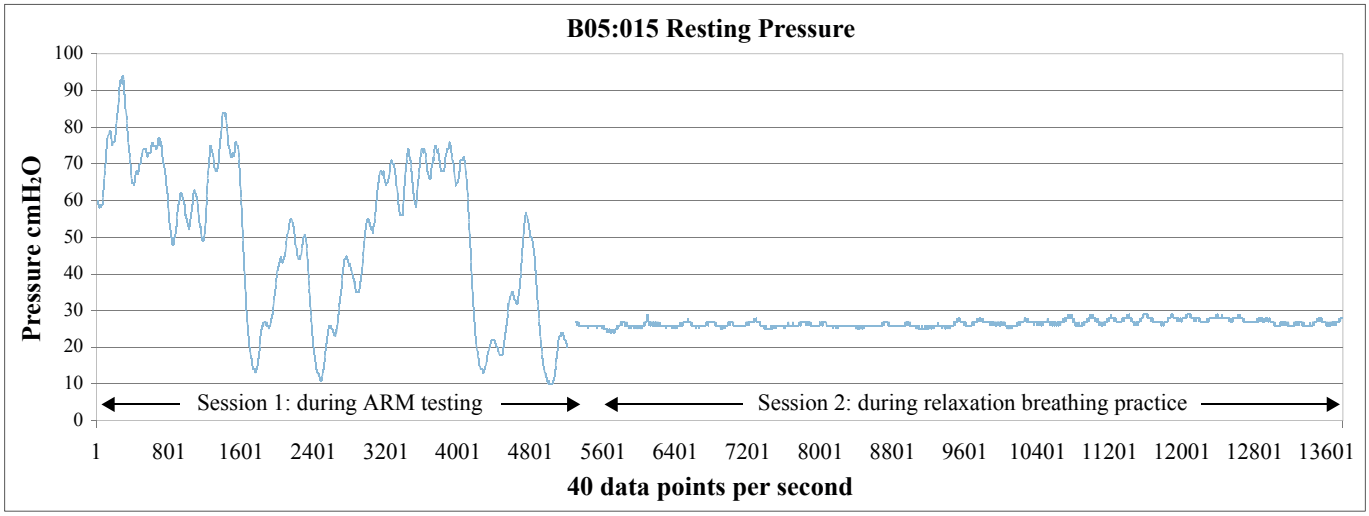
5. Vickers D, Biofeedback for Constipation and Fecal Incontinence, in *Complex Anorectal Disorders: Investigation and Management*, Wexner SZ, AP. Pescatori, M., Editor. 2005, Springer: Milan. p. 494-531.

6. Tries J, Eisman E, The use of biofeedback for pelvic floor disorders associated with a failure to relax, in *Biofeedback: A Practitioner's Guide* Schwartz M, Andrasik F, Editors. 2003, The Guilford Press: New York. p. 646-657.


B05:060 Mean Resting Pressure (Session 1)
Mean = 20cm H₂O; Variance=24.986cm H₂O
Mean =19.8cm H₂O; Variance=24.908cm H₂O
Pressure cmH₂O
40 data points per second


B05:060 Relaxation Breathing (Session 2)
Minute #1
Mean = 36cmH₂O
Variance=2.236cmH₂O
Minute #2
Mean = 36cmH₂O
Variance=1.886cmH₂O
Minute #3
Mean = 35cmH₂O
Variance=0.838cmH₂O
Pressure cmH₂O
40 data points per second




B05:015 Resting Pressure
Pressure cmH2O
100
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20
10
0
Session 1: during ARM testing
Session 2: during relaxation breathing practice
1
801
1601
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12801
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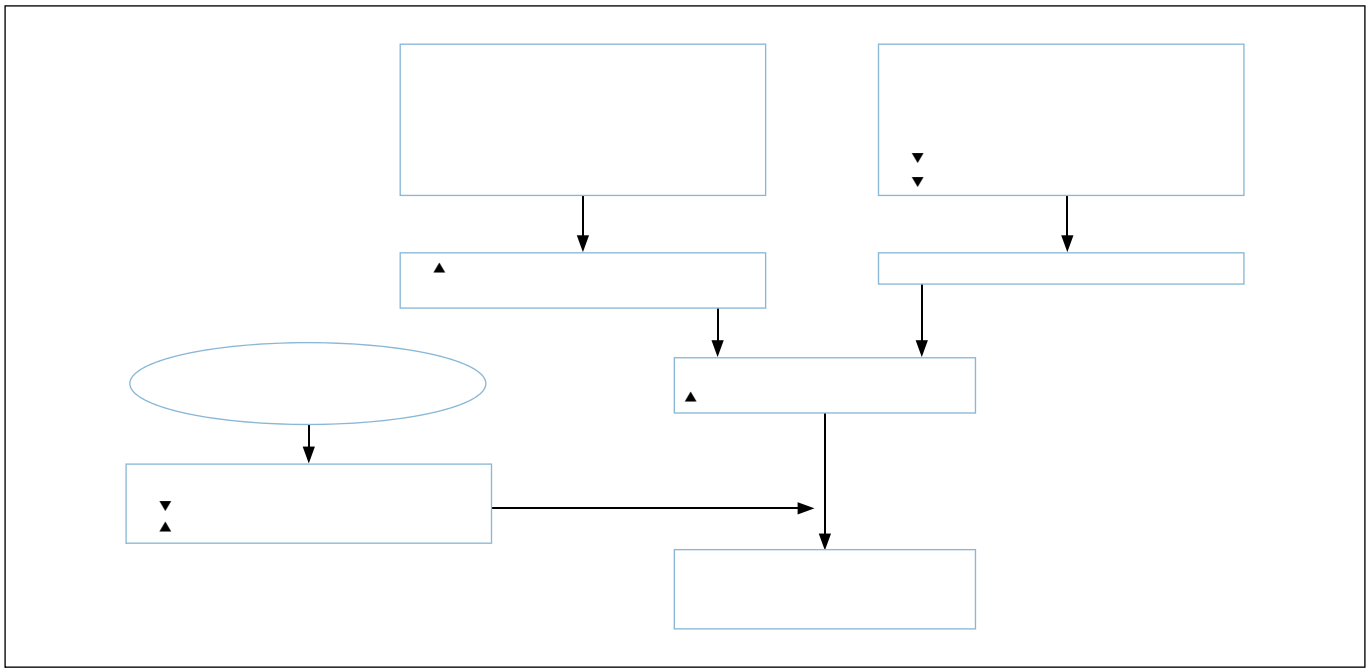
40 data points per second



6.2 Additional (unpublished) findings

Additional analyses were undertaken to explore the benefits of the relaxation breathing component of the biofeedback program by comparing the quality of life of participants who were taught relaxation breathing as the first skill of the program with those who acquired the skill later in the program.

Biofeedback study participants continence and quality of life were assessed prior to treatment sessions 1 and 2 and after their final session. In the exercise study (Chapter 5.1), relaxation breathing was taught and practiced as a standalone component in session 2. In the home biofeedback study (Chapter 5.4) it was included in session 1. This was the only difference in session 1 between the two studies.

Continence scores and quality of life scales were similar in sessions 1 and 2 of the exercise study. There was, however, a significant improvement in continence score ($P = 0.024$) and the coping scale ($P < 0.001$) between sessions 1 and 2 in the home biofeedback study (Table 6.1). Furthermore there was a significant improvement in coping between the studies (1.9% to 10.3%; $P = 0.027$; Table 6.1) below demonstrates that relaxation breathing has a statistically significant coping effect ($P = 0.027$) and at 10.3% versus 1.9% it could be termed a medically relevant improvement. Many participants (from both studies) reported the benefit of learning this skill.

This is the first report quantifying the coping benefits of relaxation breathing for people with faecal incontinence. These results justify the inclusion of relaxation breathing in holistic anorectal biofeedback therapy programs.

Table 6.1 Continence and Quality of Life: comparison by biofeedback study

Measure[1]	Study[2]	Session[3]		Improvement[3]		
		1	2	%	*P* Session 1/2	Studies
Continence score	Exercise	11.50	11.50	0.0%	0.764	0.111
	Home biofeedback	14.00	13.00	0.0%	**0.024**	
Lifestyle scale	Exercise	3.35	3.25	-2.3%	0.112	0.107
	Home biofeedback	3.30	3.34	0.0%	0.678	
Coping scale	Exercise	2.29	2.16	1.9%	0.196	**0.027**
	Home biofeedback	1.89	2.11	10.3%	**<0.001**	
Depression scale	Exercise	2.78	2.87	3.1%	0.202	0.883
	Home biofeedback	2.91	2.91	3.3%	0.076	
Embarrassment scale	Exercise	2.17	2.33	0.0%	0.197	0.820
	Home biofeedback	2.00	2.33	0.0%	0.115	

[1] Cleveland Clinic Florida Fecal Incontinence Score (Jorge 1993): 0-20(0 = Continent) ; Fecal Incontinence Quality of Life Scales (Rockwood 2000):1-4 (4 = unaffected by faecal incontinence).
[2] Exercise - Chapter 5.1; Home biofeedback – Chapter 5.4.
[3] Median value

CHAPTER 7: CONCLUSIONS, OUTCOMES AND FUTURE RESEARCH DIRECTIONS

Conclusions

The overall aim of this thesis was to expand the evidence base with regard to the disclosure, prevalence and conservative biofeedback treatment of faecal incontinence in rural and regional Australia. The Townsville Hospital, a publicly funded regional hospital with a large rural catchment area in northern Queensland, was the main setting for the clinical studies and north and far north Queensland the setting for the prevalence study.

Faecal incontinence poses a significant challenge not only to the quality of life of those with the condition, but to their carers and the economy. It is such an embarrassing and stigmatising disorder that the sufferer often denies the condition exists, calling it diarrhoea or urgency. When they do realise it is a major problem that does not resolve, sometimes decades later, they have difficulty in disclosing it to family or their general practitioner. Faecal incontinence is also a key reason and tipping point for nursing home placement when carers become overwhelmed and can no longer cope.

General health in rural populations is poorer than in urban centres. This has been linked to: lower levels of education, employment and income; occupational risks; higher levels of lifestyle diseases and risky behaviours such as smoking, alcohol abuse, and driving long distances. In addition, health services are less accessible in rural areas [1, 2]. Prior to this research most Australian studies of faecal incontinence have been conducted in metropolitan populations [3-8]. Rural areas in Australia are different from its cities, geographically, socially and economically [9]. The impact of faecal incontinence in these populations may also be dissimilar. Assembling rural evidence may enable the health gap to be narrowed.

Disclosure

Few people disclose the problem of faecal incontinence. In the 2004 disclosure study only 7 of 318 participants were referred from the urogynaecology and colorectal clinics for anorectal biofeedback treatment for faecal incontinence despite 87 disclosing the problem in the study. Similarly in the 2007 prevalence study only 7% of those reporting the condition had sought medical advice for the condition. Recommendations to enhance patient disclosure were also suggested by those who participated in the biofeedback studies. Their recommendations directed at general practitioners included: exhibit empathy, actively listen and ask patients directly about faecal incontinence; give advice about risk factors and anorectal biofeedback programs; and include standard incontinence questions in patient management software for routine check-ups to enable early identification and treatment. Surveys designed to measure prevalence should ensure that: ongoing faecal incontinence is

measured; the terminology used is not ambiguous; and isolated episodes associated with short-term illness are excluded. Embedding the questions within a questionnaire about bowel health was also suggested to minimise embarrassment and maximise disclosure. Given the high rates of faecal incontinence in patients attending urogynaecology and colorectal outpatient clinics for other reasons, information and advice about this condition should be provided routinely.

Prevalence

The prevalence of faecal incontinence is highly dependent on the definition applied [4, 10]. Overseas prevalence estimates range from 2% to 17%, with the variation being due to inconsistent definitions, poor bias minimization and lack of validated, self-administered, anonymous questionnaires [10]. Studies conducted in 2003 [11] and 2004 [Chapter 2.1] reported faecal incontinence in over 20% of the Townsville hospital colorectal and urogynaecological clinic patients. This prompted concern about the prevalence of faecal incontinence in the northern Queensland community. From a survey of community dwelling, northern Queensland adults in 2007 [Chapter 3.1], 12.7% reported faecal incontinence not due to an acute illness in the previous 12 months. When soiling with flatus and urgency were included, stool related accidental bowel leakage was 18.2%. The focussed definition which omitted bowel leakage due to a virus, medication or contaminated food had not been used previously and provided evidence that the problem was ongoing. When the broader definition (not omitting faecal incontinence due to acute illnesses) was used, prevalence was 28.1%. Rural prevalence is exceedingly high when compared to the 11% rates found in an Australian city [3, 4]; where the prevalence was measured without using a more focussed definition.

Impact on quality of life

Whilst improvement in severity (type and frequency) is one measure used to assess treatment outcomes, the burden on a patient's quality of life should also be central to any evaluation. The Fecal Incontinence Quality of Life Scale, a disease specific quality of life assessment tool, is reliable and is the measure of choice recommended to evaluate the impact of faecal incontinence on the lives of older community dwelling adults in Australia [12]. Quality of life of those with faecal incontinence was assessed using this tool in each of the clinical studies undertaken.

- The quality of life of more than 22% of surveyed patients attending the Townsville hospital urogynaecology and colorectal outpatient clinics for matters other than faecal incontinence in 2003 and 2004 was severely affected by faecal incontinence.
    - Participants who attended the colorectal clinic had poorer quality of life than those attending the urogynaecology clinic.
    - The burden on participants' lives worsened with the loss of both solid and liquid stool and the increased frequency and quantity of soiling.

  - Overall results for lifestyle (3.24), coping (2.23), depression (2.42) and embarrassment (2.33) scales were similar to comparable clinic-based studies in other countries [Chapter 4.1]
- Women with faecal incontinence surveyed found the condition significantly more embarrassing than men despite similar severity of faecal incontinence and their coping, depression and lifestyle scales being similarly affected.
- Patients referred for biofeedback had poorer quality of life and greater severity than those with the condition who attended the Townsville hospital urogynaecology and colorectal outpatient clinics for matters other than faecal incontinence. Of those (n=15) who participated in the disclosure studies and went on to receive biofeedback treatment, their severity deteriorated prior to treatment although their quality of life did not.

Biofeedback

- The biofeedback exercise study found that there were no significant differences in objective or subjective measures between the 2 exercise regimens. However, 86% of participants had improved continence with 20% cured by the end of treatment and 38% reporting no faecal leakage 2 years later. Ninety per cent of participants were very satisfied with their treatment outcomes. Both continence and quality of life scores improved significantly during treatment with the improvements maintained 2 years later.
- The biofeedback treatment program significantly improved continence and quality of life for both regional and rural participants. While severity and quality of life had continued to improve in regional participants 2 years later, the outcomes of rural participants had regressed to pre-treatment levels.
- Participants with bowel dysfunction following surgery for colorectal cancer achieved significant reduction in their symptoms after therapy using computer-guided biofeedback. This improvement in symptoms was sustained for more than 2 years following treatment. Pelvic floor muscle training using biofeedback, a key element of the program, increases awareness and understanding of the reconstructed gastrointestinal tract and its functions and enables patients to confidently manage bowel symptoms. As most of these patients enjoyed an active lifestyle before surgery, and had a strong appreciation for their health and quality of life, they were typically compliant with the advice and exercise regimens of the program.
- The supplementary home biofeedback study found that: the device with an anal sensor was acceptable and well tolerated by participants**;** the perinometer group did significantly better in the lifestyle and embarrassment FIQL scales; younger (< mean age) perineometer participants' continence and quality of life measures were significantly better than similar aged controls; and compliance with prescribed exercises for the intervention group was

excellent and yielded significant improvement in technique and performance over the course of treatment. Most perineometer participants found the device helped with the exercise program.

Relaxation breathing

- Relaxation breathing regulates pressure waves in the internal anal sphincter which may aid in the reduction of incontinent episodes and faecal urgency
- Relaxation breathing enables patients with faecal incontinence to cope better with the condition

Outcomes

Publications:

- Most of the findings in this thesis have been peer reviewed and are either published or in press

Conference presentations:

- Seven presentations of findings from this thesis at national and international conferences

Changes to policy and practice:

- Townsville hospital anorectal biofeedback clinic available to patients two days per week instead of one
- 2nd biofeedback therapist trained and employed
- Spreadsheet tool developed for the hospital clinic to provide consistently accurate results. This tool included: Cleveland Clinic Florida Fecal Incontinence score (Wexner), Fecal Incontinence Quality of Life Scale (FIQL), Gastrointestinal Quality of Life Index (Eyepasch)
- Improved resources for patients (exercise sheets)
- Embarrassing problems disclosure tool development and provided to the Townsville Division of General Practice

Recommendations

- Faecal incontinence, its prevalence, risk factors, prevention, and treatments should be widely discussed to raise community awareness in particular by:
    - Parents/educators to provide lifestyle advice to prevent chronic constipation (faecal incontinence risk factor) and encourage the development and maintenance of strong pelvic floor muscles among young people

    - Midwives during antenatal classes to help mothers retain strong pelvic floor muscles and recognise chronic constipation in themselves and their children
    - Tertiary medical, nursing and rehabilitation science educators
    - Medical software producers – to enable general practitioners to routinely question patients with risk factors
- Patients attending colorectal and urogynaecology outpatient clinics should be routinely assessed and referred if necessary for anorectal biofeedback treatment for faecal incontinence.
- Development and assessment of a faecal incontinence treatment video program for:
    - Back-up / home use of biofeedback clinic patients
    - Physiotherapists, general practitioners and other health providers in rural and remote areas without access to specialist biofeedback clinics
    - Telemedicine patients
    - Self-managed care for minor - moderate faecal incontinence of benign origins

Future research directions

The holistic biofeedback program is comprehensive with patients finding most aspects very helpful. However the one-on-one sessions take up to 2 hours. Addressing the patient's diet can be time consuming. Further research on the impact of dietary changes on faecal incontinence and development of patient educational resources is suggested.

One-on-one biofeedback is a limited resource-intensive therapy to which the vast majority of people suffering with faecal incontinence do not have access. Further research is vital to determine if a self-help video and/or website with/without home biofeedback devices could improve faecal continence and quality of life in community residing patients who have been referred for biofeedback and either:

- do not have easy access to a biofeedback clinic and can be overseen by a local doctor, nurse or therapist
- need additional support during or following the biofeedback clinic sessions
- where faecal incontinence is of benign causes, and patients are both capable and willing to self-manage their condition

References

1. Australian Institute of Health and Welfare, Australia's Health 2010., in *Australia's Health Series No. 12. Cat. No. AUS 122.* 2010, AIHW: Canberra.
2. Davis S, Bartlett H, Healthy ageing in rural Australia: issues and challenges. *Australasian Journal on Ageing*, 2008. 27(2): 56-60.
3. Lam TCF, Kennedy ML, Chen FC, Lubowski D, Talley NJ, Prevalence of faecal incontinence: obstetric and constipation risk factors: a population based study. *Colorectal Disease*, 1999. 1: 197-203.
4. Kalantar JS, Howell S, Talley NJ, Prevalence of faecal incontinence and associated risk factors; an underdiagnosed problem in the Australian community? *The Medical Journal of Australia*, 2002. 176(2): 54-7.
5. Byrne CM, Pager CK, Rex J, Roberts R, Solomon MJ, Assessment of quality of life in the treatment of patients with neuropathic fecal incontinence. *Diseases of the Colon and Rectum*, 2002. 45(11): 1431-6.
6. Solomon MJ, Rex J, Eyers AA, Stewart P, Roberts R, Biofeedback for fecal incontinence using transanal ultrasonography: novel approach. *Diseases of the Colon and Rectum*, 2000. 43(6): 788-92.
7. Solomon MJ, Pager CK, Rex J, Roberts R, Manning J, Randomized, controlled trial of biofeedback with anal manometry, transanal ultrasound, or pelvic floor retraining with digital guidance alone in the treatment of mild to moderate fecal incontinence. *Diseases of the Colon and Rectum*, 2003. 46(6): 703-10.
8. Nikoletti S, Young J, Levitt M, King M, Chidlow C, Hollingsworth S. Preventing and managing faecal incontinence after sphincter-saving surgery for colorectal cancer. *Final Report* 2003 [Revised 6 June 2008] Accessed: 9 June 2009]; Available from: http://www.bladderbowel.gov.au/ncms/projects/phases/preventandmanage.htm.
9. Wakerman J, Humphreys JS, Rural health: why it matters. *The Medical Journal of Australia*, 2002. 176(10): 457-8.
10. Macmillan AK, Merrie AE, Marshall RJ, Parry BR, The prevalence of fecal incontinence in community-dwelling adults: a systematic review of the literature. *Diseases of the Colon and Rectum* 2004. 47(8): 1341-9.

11. Ho YH, Mu ller R, Veitch C, Rane A, Durrhei m D, Faecal incontinence: an unrecognised epidemic in rural North Queensland? Results of a ho spital-based outpatient study. *Australian Journal of Rural Health*, 2005. 13(1): 28-34.

12. Fallon A, Wes taway J, Moloney C, A systematic review of psychometric evidence and expert opinion regarding the assessment of faecal i ncontinence in older community-dwelling adults. *International Journal of Evidence-Based Healthcare*, 2008. 6(2): 225-259.

Appendix 1 Disclosure study documentation

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL PATIENT SURVEY

Faecal Incontinence Research Group

Faecal incontinence is an important and often unrecognised problem in the Townsville community. In order to ensure that the best possible services are provided for affected people, the Townsville Hospital and James Cook University are collaborating to determine how many patients are affected and how faecal incontinence impacts on their daily lives. We appreciate you taking the time to complete this questionnaire. It should take no longer than 10-15 minutes to complete.

All information provided will be treated in the strictest confidence.
Should any of the questions be unclear or if you have any questions about this study, please feel free to speak to the person who handed you the questionnaire.
All completed questionnaires should be returned to this nurse.

SECTION 1

1. **Year of Birth** | 1 | 9 | | |

2. **Gender** *(please tick one)* ○ Male ○ Female

3. **If female, how many children have you had by vaginal (not cesarean) delivery?**
_____ (number)

SECTION 2

4. **Do you have any of the following medical conditions?** (tick any that are appropriate)

- ○ Diabetes
- ○ Rectal prolapse
- ○ Chronic constipation requiring prolonged straining to pass a stool
- ○ Psychiatric problems requiring ongoing medication.
  If yes, please state diagnosis _____
- ○ Colon disease. If yes, please state diagnosis _____
- ○ Spinal cord disease. If yes, please state diagnosis _____
- ○ Neurological disease. If yes, please state diagnosis _____
- ○ Urinary incontinence.
  a) If you accidentally soil with urine, how often does it occur?
  ○ Daily ○ Monthly
  ○ Weekly ○ Less often
  b) If you accidentally soil with urine, is there usually:
  ○ Just minimal soiling of your underwear (no need to immediately change underwear)
  ○ Major soiling of your underwear (need to immediately change underwear)
  ○ Soiling of outer clothes
  ○ Soiling of furniture or bedding
- ○ None of the above

LABEL

Please turn over page

5. **Have you had any of the following?** (tick any that are appropriate)

- ○ Surgery for haemorrhoids / anal fissures / anal fistulas
- ○ Vaginal repair surgery
- ○ A delivery of a baby requiring a forceps, vacuum, or stitches for a large tear during childbirth (not an episiotomy)
- ○ An injury to the anus
- ○ Radiation therapy. If yes, please state diagnosis _____
- ○ None of the above

6. **Have you consumed any alcohol in the last week?**

- ○ Yes
- ○ No. If no, how long has it been since you last consumed alcohol?____(months) (please proceed to question 8)

7. **If you consumed any alcohol in the last week, please indicate below the type and amount as a total <u>for the whole of last week.</u>**
(If you haven't drunk alcohol in the last week please proceed to **question 8.**).

- ○ Beer _____pots, cans or stubbies
- ○ Spirits _____nips
- ○ Wine _____glasses
- ○ Other, please specify _____

8. **In general would you say your health is:**

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

9. **Do you ever accidentally soil your clothes or underclothes with faeces?** (please tick one)

- ○ No (**<u>If no, you have now finished this survey</u>.** Thank-you very much for participating.)
- ○ Yes (**<u>If yes, please proceed to question</u> 10** below)

SECTION 3

10. **If you have ever accidentally soiled your clothes or underclothes with faeces, how often does this usually happen** (please tick only one)

○ Daily ○ Monthly

○ Weekly ○ Less often

11. **How many months ago did this problem start?** _____(months)

12. **How would you describe the accidental soiling?** (please tick only one)

○ Mainly watery ○ Mainly formed ○ Both

13. **How often do you accidentally soil without being aware of it at first?**

○ Always ○ Sometimes ○ Never

14. **How often do you accidentally soil after you've felt the urge to go to the toilet but weren't able to make it in time?**

○ Always ○ Sometimes ○ Never

15. **Do you usually use some method for controlling accidental soiling?** (tick all that apply)

- ○ No
- ○ A pad
- ○ Anti-diarrhoeal medication
- ○ Other, please specify the method used _____

16. **When you accidentally soil, is there usually:** (please tick only one)

- ○ Just minimal soiling of your underwear (no need to change immediately)
- ○ Major soiling of your underwear (need to immediately change underwear)
- ○ Soiling of outer clothes
- ○ Soiling of furniture or bedding

17. **Do you use any of the following** (tick any that are appropriate)

- ○ Laxatives at least three times each week
- ○ Enemas or suppositories at least three times each week
- ○ Any other object inserted into your anus (including a finger or any other body parts)
- ○ None of the above

SECTION 4

18. **For each of the statements below, please indicate *(by circling the relevant number)* how much of the time the issue is a concern for you DUE TO ACCIDENTAL BOWEL LEAKAGE.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	Most of the time	Some of the time	A little of the time	None of the time	N/A
a.	I am afraid to go out	1	2	3	4	☐
b.	I avoid visiting friends	1	2	3	4	☐
c.	I avoid staying overnight away from home	1	2	3	4	☐
d.	It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e.	I cut down on how much I eat before I go out	1	2	3	4	☐
f.	Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g.	It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h.	I avoid travelling	1	2	3	4	☐
i.	I worry about not being able to get to the toilet on time	1	2	3	4	☐
j.	I feel I have no control over my bowels	1	2	3	4	☐
k.	I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l.	I leak stool without even knowing it	1	2	3	4	☐
m.	I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

19. **<u>DUE TO ACCIDENTAL BOWEL LEAKAGE</u>, please indicate *(by circling the relevant number)* the extent to which you agree or disagree with each of the following items.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

Due to accidental bowel leakage:		Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree	N/A
a.	I feel ashamed	1	2	3	4	☐
b.	I can not do many of the things I want to do	1	2	3	4	☐
c.	I worry about bowel accidents	1	2	3	4	☐
d.	I feel depressed	1	2	3	4	☐
e.	I worry about others smelling stool on me	1	2	3	4	☐
f.	I feel like I am not a healthy person	1	2	3	4	☐
g.	I enjoy life less	1	2	3	4	☐
h.	I have sex less often than I would like to	1	2	3	4	☐
i.	I feel different from other people	1	2	3	4	☐
j.	The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k.	I am afraid to have sex	1	2	3	4	☐
l.	I avoid travelling by plane or train	1	2	3	4	☐
m.	I avoid going out to eat	1	2	3	4	☐
n.	Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

20. **During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?** (please tick only one)

- ○ Extremely so – to the point that I have just about given up
- ○ Very much so
- ○ Quite a bit
- ○ Some-enough to bother me
- ○ A little bit
- ○ Not at all

THANK YOU FOR YOUR TIME.

PLEASE RETURN YOUR COMPLETED QUESTIONNAIRE TO THE RESEARCH OFFICER.

The JCU Faecal Incontinence Research Group:

- Prof. Yik-Hong Ho, Townsville Hospital, phone: 47961417
- A/Prof. David Durrheim & A/Prof Reinhold Müller, School of Public Health, phone: 47815959
- Lynne Bartlett, School of Public Health, phone: 4796 1721

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL

PHYSICIAN SURVEY FORM

Faecal Incontinence Research Group

Continence Score (Wexner Scale):

Please mark all 5 rows with a tick as appropriate

Type of incontinence		Frequency				
		NEVER	RARELY <1/month	SOMETIMES <1/week, >1/month	USUALLY <1/day, >1/week	ALWAYS ≥1/day
❶	Solid	0	1	2	3	4
❷	Liquid	0	1	2	3	4
❸	Gas	0	1	2	3	4
❹	Wears Pad	0	1	2	3	4
❺	Lifestyle alteration	0	1	2	3	4

⇨ **Have you ever soiled your underwear with faeces?**

If no, please go to the next arrow

If yes, please indicate the frequency of soiling**:**

a. Frequency of soiling with solid stools: **Tick in ❶**

b. Frequency of soiling with liquid faeces: **Tick in ❷**

⇨ **Can you control your flatus?**

If yes, please go to next arrow

If no, on the average how often do you loose control? **Tick in ❸**

⇨ **Do you need to wear a pad for faecal incontinence?**

If no, please go to next arrow

If yes, how frequently do you wear a pad for **faecal soiling** **Tick in ❹**

⇨ **Do you have to make adjustments in your daily life because of faecal incontinence?**

If yes, how regularly do you have to make such adjustments **Tick in ❺**

LABEL

FI Interview check sheet

Thanks for completing & returning the surveys
(check for discordance Q9=No/W1 or W2 > 0 **or** W1 and W2 =0 Q9=yes)

Discordant Wexner / Q9 (W1 and W2 =0 Q9=yes) (non disclosure to doctor)	**Discordant Q9** / Wexner (Q9=No / W1 or W2 > 0) (non disclosure on Pt Completed Survey)
Permission to review – *(you may stop at any time)*	Permission to review - *(you may stop at any time)*
Comprehension of surveys? *Easy to understand?* Pt Completed Wexner (Phys) Good – Ok – Bad Good – Ok - Bad	Comprehension of surveys? *Easy to understand?* Pt Completed Wexner (Phys) Good – Ok – Bad Good – Ok - Bad
Concern re suitability of Wexner Q1/Q2 (hospital/GP surgery) *We are considering making this survey available for GP use* **Did you find the questions asked by the doctor easy to understand?** Yes / No **How did you find answering them to the doctor?** • Embarrassing • Confusing • I didn't want to discuss this with this doctor • I don't want to discuss this with any doctor • I didn't think we had time to discuss this • Other? • **If you had this bowel problem would you let your GP know?** Yes – no – don't know – did not answer **Would you mind if your GP asked these questions?** Yes – No – No answer - Other **How would you prefer to answer these questions?** • Through a patient completed survey • Telephone survey • Anonymously • Other: **If you had this bowel problem, would you seek help from:** • Your GP / other doctor? • A specially trained continence nurse	Concern re suitability (Population survey) *We are considering using this survey to find out how many people in NQ have FI in order to determine the level of services needed to help sufferers.* **How did you find the questions generally?** Difficult to understand / OK / easy to understand **Now that you have answered the survey questions put to you by the doctor would you like to change any answers on the survey you completed?** Yes / No **With regard to Q9 specifically: were you happy to answer this?** Yes / No **Potential issues** Language ie. Faeces Accidentally soil Tim ing (ever/recently) Other Disclosure to strangers em barrassment Clarity i.e. FI accident one off due to diarrhea Survey length can't be bothered – too long **If you had this bowel problem, would you seek help from:** • Your GP / other doctor? • A specially trained continence nurse

PATIENT INFORMATION SHEET

PROTOCOL NAME: **Review of A Locally Developed Self-Administered Questionnaire on Faecal Incontinence**

INVESTIGATORS: **Lynne Bartlett, Yik-Hong Ho, Reinhold Muller, Ajay Rane.**

WHAT IS THE PURPOSE OF THIS STUDY?

To get your advice on the patient completed faecal incontinence survey questions where answers do not correspond with those provided in the physician completed survey.

WHY REVIEW THE QUESTIONNAIRE?

We wish to survey the North Queensland population. To do this we must ensure that answers to the self-administered questionnaire reflect the facts. This study aims to improve and validate the locally developed survey questionnaire.

By finding out how many people are affected by faecal incontinence in the community, health agencies can make plans with regard to resources for the early detection, prevention and management of faecal incontinence

We greatly appreciate the time and advice you are giving. By assisting with this study you are helping to reduce or even remove the distress others may face through Faecal Incontinence.

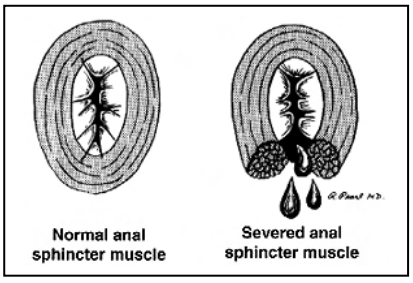
WHAT IS FAECAL INCONTINENCE?

Faecal incontinence is the involuntary loss of liquid or solid stools through the anus with or without the patient's awareness

WHAT CAUSES INCONTINENCE?

There are many causes of incontinence:

- Injuries during childbirth
- Injury to anal muscles
- Anal infections
- Diminished muscle strength with age



WHAT CAN BE DONE TO CORRECT THE PROBLEM?

After a careful history, physical examination and testing to determine the cause and severity of the problem, treatment can be given. This may include:

- Dietary changes
- Constipating medications
- Muscle strengthening exercises
- Biofeedback
- Surgical muscle repair

INVESTIGATOR CONTACT NAME: *Lynne Bartlett*

INVESTIGATOR CONTACT TELEPHONE NO: *07 4796 1721*

DATED: *October / November 2004*

SIGNATURE OF CONTACT INVESTIGATOR:

Investigators are responsible for including an appropriate statement regarding payments to subjects on the Information Sheet

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has been removed

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has been removed

Queensland Government

Queensland **Health**

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Appendix 2 Prevalence study documentation

SECTION 1: PERSONAL DETAILS

Firstly we would like to ask you some questions about your background:

1. How old are you? _____ Years

2. Are you? ☐ Male ☐ Female

3. Do you live with anyone?

☐ No, alone
☐ Yes, with
☐ Spouse/Partner ☐ Parents
☐ Children ☐ Other family
☐ Other _____

4. What type of residence do you live in?

☐ House ☐ Apartment / Unit
☐ Caravan ☐ Retirement village
☐ Other_____

5. What is your postcode? _____

6. What is your highest education level?

☐ Primary School
☐ Secondary School
☐ Trade Certificate
☐ College Diploma
☐ University degree
☐ Postgraduate degree
☐ Other_____

7. What is your current occupation?

☐ Student ☐ Unemployed
☐ Labourer ☐ Tradesperson
☐ Homemaker ☐ Clerical
☐ Professional ☐ Retired
☐ Other _____

8. What is your country or region of birth?

☐ Australia

☐ACT ☐NSW ☐VIC ☐QLD ☐SA ☐WA ☐TAS ☐ NT

☐ United Kingdom ☐ Europe
☐ Asia ☐ Pacific Region
☐ USA / Canada ☐ Africa
☐ Other _____

9. What is your height?

___ : ___ metres or ___ feet ___ inches

10. What is your weight?

_____ : ___ kg or _____ st ___ lbs

Please continue with question 11 ↑

11. Are you of Aboriginal, Torres Strait or South Sea Islander descent?

☐ No ☐ Yes
☐ Aboriginal ☐ Torres Strait Islander
☐ South Sea Islander

If you are female, please also answer questions 12 – 19 below:

If male, please continue with question 20

12. Are you?

☐ Pre-menopausal
☐ Menopausal
☐ Post-menopausal
☐ I am not sure

13. How many children have you given birth to? _____

14. How many of these children were by caesarean section? _____

15. Have you given birth to a baby requiring?

☐ Forceps delivery ☐ Not applicable
☐ Vacuum extraction

16. During delivery of a baby have you had an episiotomy *(Deliberate incision made by a doctor)*?

☐ Yes ☐ No ☐ Not applicable

17. After delivery of a baby have you had stitches for a large tear? (Not including an episiotomy)

☐ Yes ☐ No ☐ Not applicable

18. Have you had a hysterectomy *(removal of the uterus/womb)*?

☐ Yes ☐ No

19. Are you taking Hormone Replacement Therapy *(HRT/oral estrogen)*?

☐ Yes ☐ No
☐ I used to but stopped ____ years ago

SECTION 2: HEALTH FACTORS

The questions in this section are about your current and past health conditions.

20. Have you been diagnosed with any of the following medical conditions? *(Tick if yes)*

- ☐ Diabetes
  - ☐ Type 1 (insulin dependent)
  - ☐ Type 2 (Non insulin dependent)
- ☐ Thyroid disease
- ☐ Crohns disease/ulcerative colitis
- ☐ Coeliac disease
- ☐ Irritable bowel syndrome
- ☐ Inflammatory bowel disease
- ☐ Diverticulitis
- ☐ Traumatic injury to the anus
- Haemorrhoids in the past 12 months
  ☐ Rarely ☐ Sometimes ☐ Often
- ☐ Colon disease
  Diagnosis? _____
- ☐ Spinal cord disease
  Diagnosis? _____
- ☐ Neurological disease
  Diagnosis? _____
- ☐ Cancer Type? _____
- Pelvic organ prolapse
  ☐ Uterus ☐ Vagina
  ☐ Rectum ☐ Bladder
- ☐ Psychiatric problems requiring medication
  Diagnosis _____

☐ **I HAVE NOT HAD ANY OF THE ABOVE CONDITIONS**

21. Have you had any of the following operations? *(Please tick)*

Prolapse repair surgery
☐ Yes ☐ No

If yes was it for?
☐ Cystocele *(Bladder)* ☐ Uterine *(Uterus)*
☐ Vaginal ☐ Rectocele *(rectum)*

Abdominal or pelvic surgery
Appendectomy *(Appendix)* ☐ Yes ☐ No
Cholecystectomy *(Gallbladder)* ☐ Yes ☐ No

Bowel Surgery?
Colectomy *(Colon)* ☐ Yes ☐ No

Other surgery for anal conditions?
Haemorrhoids (ever) ☐ Yes ☐ No
Anal fissures *(split/tear)* ☐ Yes ☐ No
Anal fistulas *(skin opening)* ☐ Yes ☐ No

Spinal surgery? ☐ Yes ☐ No

☐ **I HAVE NOT HAD ANY OF THE ABOVE OPERATIONS**

22. During the last 12 months have you leaked urine? *(Please tick)*

☐ Yes ☐ No *(go to question 23)*

☐ When I cough, sneeze or laugh or do physical exercise

☐ When I get a sudden need to urinate and I can't hang on long enough

How often do you accidentally leak urine?
☐ Daily ☐ Weekly ☐ Monthly ☐ Less often

How much urine do you leak? *(Tick one)*
☐ Few drops *(no need to change underwear)*
☐ Small amount *(need to change underwear)*
☐ Moderate amount *(change more clothes)*
☐ Large amount *(change clothes/mop floor)*

23. Have you ever had a colonoscopy? ***(A test to look into the rectum and colon)***

☐ No
☐ Yes, what year? _____

Were the results normal? ☐ Yes ☐ No
Was a polyp(s) removed? ☐ Yes ☐ No

24. Do you take any of the following medications/supplements? *(Please tick)*

☐ Metamucil ☐ Citrucel ☐ Konsyl ☐ Lomotil ☐ Psyllium husk
☐ Imodium ☐ Codeine ☐ Laxatives ☐ mineral oil
☐ **NONE OF THESE**

25. How would you describe your overall health at present? *(Please tick one)*

☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good

In this section we would like to know about your bowel habits and how they affect you.

26. In the past month, how often did you usually open your bowels? *(Tick one)*

- ☐ Twice per week or less
- ☐ 3 – 4 times per week
- ☐ Once per day
- ☐ 2 – 3 times per day
- ☐ More than 4 times per day

27. Do you have a bowel movement at a regular hour? *(Tick one)*

- ☐ Always irregular
- ☐ I tend to be irregular
- ☐ 50 / 50 regular/irregular
- ☐ I tend to be regular
- ☐ Regular

28. From the Bristol stool form scale below, what type are your stools / bowel motions usually?

Type_____

The Bristol Stool Form Scale

Type 1		Separate hard lumps, like nuts (hard to pass)
Type 2		Sausage-shaped, but lumpy
Type 3		Like a sausage but with cracks on the surface
Type 4		Like a sausage or snake, smooth and soft
Type 5		Soft blobs with clear-cut edges (passed easily)
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces, ENTIRELY LIQUID

29. When you feel the need to have a bowel motion, how long can you wait before going? *(Tick one)*

- ☐ I need to go immediately
- ☐ A few minutes only
- ☐ For at least 15 minutes

30. Do you ever have a bowel motion within 1 hour of a previous motion? *(Tick one)*

☐ Never ☐ Occasionally
☐ Half the time ☐ Often ☐ Always

Please continue with question 31 ↑

31. Do you have difficulty emptying your bowels completely? *(Tick one)*

☐ Never ☐ Occasionally
☐ Half the time ☐ Often ☐ Always

32. Can you feel the difference between gas and solid stool before you pass it? *(Tick one)*

☐ Never ☐ Occasionally
☐ Half the time ☐ Often ☐ Always

33. Do your bowel movements alternate between diarrhoea and constipation?

☐ Never ☐ Occasionally
☐ Half the time ☐ Often ☐ Always

34. How much time do you spend at the toilet for your bowels each day? *(Tick one)*

- ☐ Less than 5 minutes
- ☐ 5 – 15 minutes
- ☐ 15 – 30 minutes
- ☐ 30 minutes to 1 hour
- ☐ More than 1 hour

35. Do you read while on the toilet?

☐ No ☐ Yes
If yes, why?_____

36. How often do you have to strain when having a bowel motion? *(Tick one)*

☐ Never ☐ Occasionally
☐ Half the time ☐ Often ☐ Always

37. How strongly must you strain to have a bowel motion? *(Tick one)*

☐ Not at all ☐ A little
☐ Somewhat ☐ Very hard

38. How long do you strain in order to have a bowel motion? *(Tick one)*

☐ Do not strain ☐ Less than 1 minute
☐ 1-2 minutes ☐ 2-5 minutes
☐ 5-10 minutes ☐ More than 10 minutes

39. Do you get a pain in the abdomen when having a bowel movement? *(Tick one)*

☐ Never ☐ Occasionally
☐ Half the time ☐ Often ☐ Always

40. Do you have a history of constipation?

☐ No ☐ Yes; if yes, for how long?

☐ Less than 1 year ☐ 1 – 5 years
☐ 5 – 10 years ☐ 10 – 20 years
☐ More than 20 years

41. How many times in the past 12 months have you visited a doctor for problems with your bowels?

____times for constipation

____times for bowel leakage

____times for other?_____

42. Have you **ever** been hospitalized for **colon** (large bowel) **blockage** from constipation (disimpaction of stool)?

☐ No ☐ Yes: How many times? _____

43. Can you break wind without soiling your underclothes? *(Tick one)*

☐ No, never ☐ Yes, sometimes
☐ Yes, often ☐ Yes, always

Please continue with question 44 ↑

44. How often does soiling happen when you break wind involuntarily? *(Tick one)*

☐ Never ☐ Less than once a month
☐ Between once a month and once a week
☐ Between once a week and once a day
☐ More than once a day

45. Please indicate *(circle), for the past 12 months*, how your bowel function affected each of the following activities:

Activity	Amount affected			
	Not at all	Mildly	Moderately	Severely
Sports/Recreation	1	2	3	4
House/Garden work	1	2	3	4
Social/Entertainment	1	2	3	4
Family relationships	1	2	3	4
Travel	1	2	3	4
Sexual life	1	2	3	4
Work (Occupational)	1	2	3	4
Daily Living	1	2	3	4

46. In the past 12 months have you ever soiled your clothes or underwear through bowel leakage due to a reaction to a virus, medication or bad food? *(Tick one)*

☐ Never ☐ Once or twice ☐ 3 – 5 times ☐ More than 5 times

47. In the past 12 months and **not due** to a reaction to a virus, medication or bad food, please tick how often you have had accidental bowel leakage and what type?

Type of accidental bowel leakage	Frequency				
	Never	Rarely	Sometimes	Usually	Always
		Less than once per month	More than once per month and less than once per week	More than once per week and less than once per day	Once or more per day
SOLID					
LIQUID					
MUCUS					
GAS (WIND)					
Please tick how often you wear a pad to protect your clothes against bowel leakage					
During the day					
At night					
Please tick how often you make adjustments to your lifestyle because of:					
Bowel leakage					

If you have answered **never to every section in the above table** please go to question **55**

48. How many months / years ago did the bowel leakage begin? _____years ____months

49. Are you bothered about the bowel leakage?

☐ Not at all ☐ Slightly ☐ Moderately ☐ Greatly

50. How often do you have accidental bowel leakage without being aware of it at first?

☐ Never ☐ Sometimes ☐ Always

51. How often do you have accidental bowel leakage after you feel the urge to go to the toilet?

☐ Never ☐ Sometimes ☐ Always

52. Do you ever have any bowel leakage at night?

☐ Never ☐ Sometimes ☐ Always

53. Have you had treatment for bowel leakage? ☐ No ☐ Yes

If no, why not?_____

54. Which local non-surgical bowel leakage health care provider would you prefer to use?

☐ GP ☐ Physiotherapist ☐ Community Health ☐ Home-based program managed by a specialist bowel clinic

55. Have any of the following conditions been a problem for you in the **past month**?

Condition	**Not at all**	**A little**	**Quite a bit**	**Very much**	**Can't recall**
Pain in or around the back passage *(anal canal/anus)*					
Bleeding from back passage *(anus)*					
Knowing what to eat to control your bowel					
Knowing what medicines to take to control your bowel					
Being able to find toilets, away from home					
Being worried whether you smell ***(due to your bowels)***					
Feeling you have no control over your bowel					
Staining of your underwear					

56. To assist with toileted bowel motions or control of accidental bowel leakage, do you use:

☐ Anti-diarrhoeal medication ☐ Laxatives (at least three times per week)
☐ Enemas or suppositories (at least three times per week)
☐ A continence aid inserted in the anus, or use pressure or a finger in the anus/vagina
☐ Other, please specify _____
☐ None used

57. Do you have first degree relatives *(Mother, father, brothers, sisters, or adult children)* who have problems with their bowels?

☐ No ☐ Yes: Relation to you?_____

What is the problem? ☐ Constipation ☐ Diarrhoea ☐ Faecal incontinence
☐ Abdominal pain ☐ Other _____

SECTION 4: NUTRITION – FIBRE AND FLUID INTAKE 2007 NQ Bowel Habit Project

In this section we would like to know how much fibre and fluid you consume.

58. Please indicate what drinks and water and the amount you drink on an average day:
(1 can = 0.375 litres, 1 cup = 0.25 litres, 1 mug = 0.3 litre, medium glass = 0.2 litres)

Volume of water
litres

Caffeinated drinks		**Volume**	**Non-Caffeinated drinks**		**Volume**
Coffee	☐	litres	Decaff. Tea/Coffee	☐	litres
Tea	☐	litres	Fruit juice	☐	litres
Cola	☐	litres	Sugared soft drink	☐	litres
Diet Cola	☐	litres	Diet soft drink	☐	litres
Other	☐	litres	Other (Beer/wine etc)	☐	litres

59. Please pick the foods you eat at home and circle your score.

FIBRE SCORE / FOOD	1	2	3	Circle your score
Breakfast Cereal *(3+ times per week)*	Rarely or never eat, or eat sugar coated cereal	Corn flakes, puffed rice	Bran flakes, oats, whole-wheat flakes, muesli	1 2 3
Bread *(3+ times per week)*	Rarely or never eat	White	Wholemeal/Grain	1 2 3
Potatoes, Pasta, Rice	Rarely or never eat	Eat potatoes, white rice or pasta most days	Eat potatoes in jackets, brown rice or pasta most days	1 2 3
Nuts & Pulses *(Peas / Beans / Lentils)*	Rarely or never eat	Once a week or less	Three times a week or more	1 2 3
Vegetables *(all kinds other than pulses & potatoes)*	Less than once a week	1–3 times per week	Daily	1 2 3
Fruit *(all kinds)*	Less than once a week	1–3 times per week	Daily	1 2 3
Fibre supplements	Rarely or never take	1–3 times per week	Daily	1 2 3

SECTION 5: PHYSICAL ACTIVITY LEVEL

2007 NQ Bowel Habit Project

We are interested in the physical activities you do as part of your everyday life.

60. What does your work or daily activity mainly involve? *(Tick one)*

☐ Sitting ☐ Standing ☐ Walking or other physical activity
☐ Heavy labour (e.g. heavy lifting or digging) ☐ Other _____

61. Outside of your normal work or daily activities, how often do you exercise for 30 minutes or more, such as walking, cycling, running or swimming)? *(Tick one)*

☐ Seldom or never ☐ Less than once a week ☐ 1-2 times a week
☐ 3-5 times a week ☐ 6 or more times a week

62. Finally we would like to know if you perform pelvic floor muscle exercises.

☐ No
☐ Yes: number per day? _____, and on 1 2 3 4 5 6 7 days per week? (circle)
☐ I do not know how to perform this exercise

Comments:_____

_____

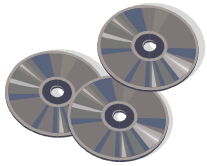
_____

_____

THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE AND MAKING A VALUABLE CONTRIBUTION TO OUR RESEARCH.

Please place the completed questionnaire and entry form in the stamped addressed envelope provided and mail to us at:

2007 Bowel Habit Project, Anton Breinl Centre,
School of Public Health, Tropical Medicine & Rehabilitation Sciences,
Reply Paid 109, James Cook University, Townsville, QLD 4811



To be drawn on Friday 12th October 2007 at 2pm

WIN $250

WIN a major prize of a $250 voucher

or one of 10 minor prizes of a $50 voucher from your choice of Coles Myer (Target/Coles/K-Mart) or BCF or Sanity/HMV/Virgin

WIN $50

TO THANK YOU

- For taking the time to complete the attached questionnaire, we are offering you the opportunity to be in the draw to win the major prize of a $250 voucher or one of 10 $50 vouchers
- Please fill in your name and contact details at the bottom of this page, cut it off and seal in the little yellow envelope, mail it and the completed questionnaire in the white reply paid envelope

Anonymity

- The unopened yellow envelope will be separated from the questionnaire as soon as we receive it
- You will not be identifiable from information you supply in the questionnaire
- Answers will be pooled, only collective data will be reported

✂

CONTACT DETAILS

Name: .....

Address: .....

.....

Phone:

(AH) .....

(Mob) .....

2007 Bowel Habit Survey: Anton Breinl Centre, James Cook University, QLD 4811

JAMES COOK UNIVERSITY
TOWNSVILLE Queensland 4811 Australia Telephone: (07) 4781 4111

2007 NORTH QUEENSLAND BOWEL HABIT PROJECT

Funded by the Queensland Cancer Fund "George Roberts" Scholarship

INFORMATION SHEET

We would like to invite you to help us identify the current bowel health status of North Queensland adults. Participation in this study is **completely voluntary**, but by doing so, you will be helping us predict the bowel health needs of North Queensland adults as they age, as well as the demand for bowel health services. The more participation we receive, the better the results will be. Your name was randomly selected from the 2007/2008 telephone directory.

If you wish to help with our research and agree to participate, please complete the enclosed questionnaire, which should take 10 - 15 minutes of your time. Finally, please return it to us, as soon as you can, in the enclosed reply paid envelope.

We understand that the information you are giving is very personal. We would like to assure you that your information is not identifiable. Please **do not** write your name on the questionnaire. The results of all the returned questionnaires will be combined to meet our aims.

All the information collected during this study will remain confidential and, in keeping with ethics guidelines all data will be locked in a secure location at the University. The principle investigator is a postgraduate public health student undertaking this research project as part of her doctorate. Only the investigator and her supervisors will have access to this information.

Should you have any concerns about your bowels please contact your local GP or the National Continence Helpline on 1800 33 00 66. If you have questions about the study, please contact Lynne Bartlett.

Lynne Bartlett (Principal Investigator)
Anton Breinl Centre, The Townsville Hospital
James Cook University
Email: lynne.bartlett@jcu.edu.au
Phone: 4796 1721

Professor Yik-Hong Ho (Principal supervisor)
Professor of Surgery,
School of Medicine, James Cook University
Email: yikhong.ho@jcu.edu.au

Dr Madeleine Nowak (Supervisor)
Anton Breinl Centre, The Townsville Hospital
James Cook University
Email: madeleine.nowak@jcu.edu.au

Professor Richard Speare (Supervisor)
Director of Anton Breinl Centre
School of Public Health, Tropical Medicine and Rehabilitation Sciences
James Cook University
Email: richard.speare@jcu.edu.au

If you have any questions about the ethical conduct of this study, please contact the Human Ethics Committee:

Tina Langford, Ethics Officer
James Cook University, Townsville, QLD 4811
Email: Tina.Langford@jcu.edu.au
Phone: 4781 4342

JAMES COOK UNIVERSITY
TOWNSVILLE Queensland 4811 Australia Telephone: (07) 4781 4111

17th September 2007

«Initials» «Surname»
«Address»
«Suburb» «State» «Postcode»

Dear «Initials» «Surname»,

2007 North Queensland Bowel Habit Project

During July I sent you a copy of this survey. If you have completed and returned it I would like to thank you very much for doing so.

If you haven't completed it, was it because?

- you were too busy
- you were not interested in the topic
- you felt that the topic was not relevant to you.

Health research is extremely important for planning resource allocation. It is vitally important that we get information from people who do not have any bowel problems as well as from those who do, so that the size of any of these problems is not overstated in the population.

Please will you complete and return the enclosed survey? If you do not have time to complete the whole survey, it would be of great help if you could complete sections 1 and 3. If you do not wish to complete the study questions, please fill in section A: non participation details

Thanking you in anticipation,

Lynne Bartlett (Principal Investigator)
Anton Breinl Centre,
School of Public Health, Tropical Medicine and Rehabilitation Sciences
Ph: 4796 1721

2007 NQ Bowel Habit Survey - Response Card

I do not wish to be contacted again because:

- ☐ I have already completed the survey
- ☐ I have no bowel problems
- ☐ This topic is too personal
- ☐ I am not interested
- ☐ I have no time to complete the survey
- ☐ Other: .....

I am:

☐ Male ☐ Female Aged:..... Postcode:..... «Ref_ID»

JCU
JAMES COOK UNIVERSITY

Delivery Address:
PO Box 109
JAMES COOK UNIVERSITY QLD 4811

No stamp required
if posted in Australia

2007 Bowel Habit Project
Anton Breinl Centre
SPHTMRS
Reply Paid 109
JAMES COOK UNIVERSITY QLD 4811

This administrative form
has been removed

This administrative form
has been removed

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has been removed

Appendix 3 Biofeedback randomised control trial documentation

Postcode: _____

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL PATIENT SURVEY

Faecal Incontinence Research Group

Faecal incontinence is an important and often unrecognised problem in the Townsville community. In order to ensure that the best possible services are provided for affected people, the Townsville Hospital and James Cook University are collaborating to determine how many patients are affected and how faecal incontinence impacts on their daily lives. We appreciate you taking the time to complete this questionnaire. It should take no longer than 10-15 minutes to complete.

All information provided will be treated in the strictest confidence.
Should any of the questions be unclear or if you have any questions about this study, please feel free to speak to the person who handed you the questionnaire.
All completed questionnaires should be returned to this research officer.

SECTION 1

1. **Year of Birth** | 1 | 9 | | |

2. **Gender** *(please tick one)* ○ Male ○ Female

3. **If female, how many children have you had by vaginal (not cesarean) delivery?**
_____ (number)

SECTION 2

4. **Do you have any of the following medical conditions?** (tick any that are appropriate)

- ○ Diabetes
- ○ Rectal prolapse
- ○ Chronic constipation requiring prolonged straining to pass a stool
- ○ Psychiatric problems requiring ongoing medication.
  If yes, please state diagnosis _____
- ○ Colon disease. If yes, please state diagnosis _____
- ○ Spinal cord disease. If yes, please state diagnosis _____
- ○ Neurological disease. If yes, please state diagnosis _____
- ○ Urinary incontinence.
  a) If you accidentally soil with urine, how often does it occur?
  ○ Daily ○ Monthly
  ○ Weekly ○ Less often
  b) If you accidentally soil with urine, is there usually:
  ○ Just minimal soiling of your underwear (no need to immediately change underwear)
  ○ Major soiling of your underwear (need to immediately change underwear)
  ○ Soiling of outer clothes
  ○ Soiling of furniture or bedding
- ○ None of the above

LABEL

5. **Have you had any of the following?** (tick any that are appropriate)

- ○ Surgery for haemorrhoids / anal fissures / anal fistulas
- ○ Vaginal repair surgery
- ○ A delivery of a baby requiring a forceps, vacuum, or stitches for a large tear during childbirth (not an episiotomy)
- ○ An injury to the anus
- ○ Radiation therapy. If yes, please state diagnosis _____
- ○ None of the above

6. **Have you consumed any alcohol in the last week?**

- ○ Yes
- ○ No. If no, how long has it been since you last consumed alcohol?____(months) (please proceed to question 8)

7. **If you consumed any alcohol in the last week, please indicate below the type and amount as a total <u>for the whole of last week.</u>**
(If you haven't drunk alcohol in the last week please proceed to **question 8.**).

- ○ Beer _____pots, cans or stubbies
- ○ Spirits _____nips
- ○ Wine _____glasses
- ○ Other, please specify _____

8. **In general would you say your health is:**

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

9. **Do you ever accidentally soil your clothes or underclothes with faeces?** (please tick one)

- ○ No (**<u>If no, you have now finished this survey</u>.** Thank-you very much for participating.)
- ○ Yes (**<u>If yes, please proceed to question</u> 10** below)

SECTION 3

10. **If you have ever accidentally soiled your clothes or underclothes with faeces, how often does this usually happen** (please tick only one)

○ Daily ○ Monthly

○ Weekly ○ Less often

11. **How many months ago did this problem start?** _____(months)

12. **How would you describe the accidental soiling?** (please tick only one)

○ Mainly watery ○ Mainly formed ○ Both

13. **How often do you accidentally soil without being aware of it at first?**

○ Always ○ Sometimes ○ Never

14. **How often do you accidentally soil after you've felt the urge to go to the toilet but weren't able to make it in time?**

○ Always ○ Sometimes ○ Never

15. **Do you usually use some method for controlling accidental soiling?** (tick all that apply)

- ○ No
- ○ A pad
- ○ Anti-diarrhoeal medication
- ○ Other, please specify the method used _____

16. **When you accidentally soil, is there usually:** (please tick only one)

- ○ Just minimal soiling of your underwear (no need to change immediately)
- ○ Major soiling of your underwear (need to immediately change underwear)
- ○ Soiling of outer clothes
- ○ Soiling of furniture or bedding

17. **Do you use any of the following** (tick any that are appropriate)

- ○ Laxatives at least three times each week
- ○ Enemas or suppositories at least three times each week
- ○ Any other object inserted into your anus (including a finger or any other body parts)
- ○ None of the above

SECTION 4

18. **For each of the statements below, please indicate *(by circling the relevant number)* how much of the time the issue is a concern for you DUE TO ACCIDENTAL BOWEL LEAKAGE.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	Most of the time	Some of the time	A little of the time	None of the time	N/A
a.	I am afraid to go out	1	2	3	4	☐
b.	I avoid visiting friends	1	2	3	4	☐
c.	I avoid staying overnight away from home	1	2	3	4	☐
d.	It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e.	I cut down on how much I eat before I go out	1	2	3	4	☐
f.	Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g.	It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h.	I avoid travelling	1	2	3	4	☐
i.	I worry about not being able to get to the toilet on time	1	2	3	4	☐
j.	I feel I have no control over my bowels	1	2	3	4	☐
k.	I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l.	I leak stool without even knowing it	1	2	3	4	☐
m.	I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

19. **<u>DUE TO ACCIDENTAL BOWEL LEAKAGE</u>, please indicate *(by circling the relevant number)* the extent to which you agree or disagree with each of the following items.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

Due to accidental bowel leakage:		Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree	N/A
a.	I feel ashamed	1	2	3	4	☐
b.	I can not do many of the things I want to do	1	2	3	4	☐
c.	I worry about bowel accidents	1	2	3	4	☐
d.	I feel depressed	1	2	3	4	☐
e.	I worry about others smelling stool on me	1	2	3	4	☐
f.	I feel like I am not a healthy person	1	2	3	4	☐
g.	I enjoy life less	1	2	3	4	☐
h.	I have sex less often than I would like to	1	2	3	4	☐
i.	I feel different from other people	1	2	3	4	☐
j.	The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k.	I am afraid to have sex	1	2	3	4	☐
l.	I avoid travelling by plane or train	1	2	3	4	☐
m.	I avoid going out to eat	1	2	3	4	☐
n.	Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

20. **During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?** (please tick only one)

- ○ Extremely so – to the point that I have just about given up
- ○ Very much so
- ○ Quite a bit
- ○ Some-enough to bother me
- ○ A little bit
- ○ Not at all

THANK YOU FOR YOUR TIME.

PLEASE RETURN YOUR COMPLETED QUESTIONNAIRE TO THE RESEARCH OFFICER.

The JCU Faecal Incontinence Research Group:

- Prof. Yik-Hong Ho, Townsville Hospital, phone: 4796 1417
- Prof. Craig Veitch, School of Medicine, phone: 4781 6408
- Lynne Bartlett, School of Public Health, phone: 4796 1721

Date: ___ / ___ /

James Cook University

TOWNSVILLE HOSPITAL

PHYSICIAN SURVEY FORM

Faecal Incontinence Research Group

Continence Score (Wexner Scale):

Please mark all 5 rows with a tick as appropriate

Type of incontinence		*Frequency*					
		NEVER	**RARELY** <1/month	**SOMETIMES** <1/week, >1/month	**USUALLY** <1/day, >1/week	**ALWAYS** >1/day	**TOTAL**
❶	Solid	0	1	2	3	4	
❷	Liquid	0	1	2	3	4	
❸	Gas	0	1	2	3	4	
❹	Wears Pad	0	1	2	3	4	
❺	Lifestyle alteration	0	1	2	3	4	
	TOTAL						

Have you ever soiled your underwear with <u>solid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Have you ever soiled your underwear with <u>liquid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Can you control your flatus? ☐ Yes ☐ No

⇨ (If yes) On average how often would you lose control

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you need to wear a pad for <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how frequently do you wear a pad for faecal soiling

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you have to make adjustments in your daily life because of <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how regularly do you have to make such adjustments

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

LABEL

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL PATIENT SURVEY

Faecal Incontinence Research Group

Q1. **In general would you say your health is?**

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

Q2. For each of the statements below, please indicate *(by circling the relevant number)* how much of the time the issue is a concern for you **due to accidental bowel leakage.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**	**N/A**
a.	I am afraid to go out	1	2	3	4	☐
b.	I avoid visiting friends	1	2	3	4	☐
c.	I avoid staying overnight away from home	1	2	3	4	☐
d.	It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e.	I cut down on how much I eat before I go out	1	2	3	4	☐
f.	Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g.	It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h.	I avoid travelling	1	2	3	4	☐
i.	I worry about not being able to get to the toilet on time	1	2	3	4	☐
j.	I feel I have no control over my bowels	1	2	3	4	☐
k.	I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l.	I leak stool without even knowing it	1	2	3	4	☐
m.	I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

LABEL

Please turn over page

Q3. **DUE TO ACCIDENTAL BOWEL LEAKAGE, please indicate *(by circling the relevant number)* the extent to which you agree or disagree with each of the following items.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree	N/A
a.	I feel ashamed	1	2	3	4	☐
b.	I can not do many of the things I want to do	1	2	3	4	☐
c.	I worry about bowel accidents	1	2	3	4	☐
d.	I feel depressed	1	2	3	4	☐
e.	I worry about others smelling stool on me	1	2	3	4	☐
f.	I feel like I am not a healthy person	1	2	3	4	☐
g.	I enjoy life less	1	2	3	4	☐
h.	I have sex less often than I would like to	1	2	3	4	☐
i.	I feel different from other people	1	2	3	4	☐
j.	The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k.	I am afraid to have sex	1	2	3	4	☐
l.	I avoid traveling by plane or train	1	2	3	4	☐
m.	I avoid going out to eat	1	2	3	4	☐
n.	Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

Q4. **During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?** (Please tick only one)

- ○ Extremely so – to the point that I have just about given up
- ○ Very much so
- ○ Quite a bit
- ○ Some-enough to bother me
- ○ A little bit
- ○ Not at all

Date: ___ / ___ /

James Cook University

TOWNSVILLE HOSPITAL

PHYSICIAN SURVEY FORM

Faecal Incontinence Research Group

Continence Score (Wexner Scale):

Please mark all 5 rows with a tick as appropriate

Type of incontinence		*Frequency*					
		NEVER	**RARELY** <1/month	**SOMETIMES** <1/week, >1/month	**USUALLY** <1/day, >1/week	**ALWAYS** >1/day	**TOTAL**
❶	Solid	0	1	2	3	4	
❷	Liquid	0	1	2	3	4	
❸	Gas	0	1	2	3	4	
❹	Wears Pad	0	1	2	3	4	
❺	Lifestyle alteration	0	1	2	3	4	
	TOTAL						

Have you ever soiled your underwear with <u>solid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Have you ever soiled your underwear with <u>liquid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Can you control your flatus? ☐ Yes ☐ No

⇨ (If yes) On average how often would you lose control

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you need to wear a pad for <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how frequently do you wear a pad for faecal soiling

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you have to make adjustments in your daily life because of <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how regularly do you have to make such adjustments

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

LABEL

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL PATIENT SURVEY

Faecal Incontinence Research Group

Q1. **In general would you say your health is?**

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

Q2. For each of the statements below, please indicate *(by circling the relevant number)* how much of the time the issue is a concern for you **due to accidental bowel leakage.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**	**N/A**
a.	I am afraid to go out	1	2	3	4	☐
b.	I avoid visiting friends	1	2	3	4	☐
c.	I avoid staying overnight away from home	1	2	3	4	☐
d.	It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e.	I cut down on how much I eat before I go out	1	2	3	4	☐
f.	Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g.	It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h.	I avoid travelling	1	2	3	4	☐
i.	I worry about not being able to get to the toilet on time	1	2	3	4	☐
j.	I feel I have no control over my bowels	1	2	3	4	☐
k.	I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l.	I leak stool without even knowing it	1	2	3	4	☐
m.	I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

LABEL

Please turn over page

Q3. **DUE TO ACCIDENTAL BOWEL LEAKAGE, please indicate *(by circling the relevant number)* the extent to which you agree or disagree with each of the following items.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree	N/A
a.	I feel ashamed	1	2	3	4	☐
b.	I can not do many of the things I want to do	1	2	3	4	☐
c.	I worry about bowel accidents	1	2	3	4	☐
d.	I feel depressed	1	2	3	4	☐
e.	I worry about others smelling stool on me	1	2	3	4	☐
f.	I feel like I am not a healthy person	1	2	3	4	☐
g.	I enjoy life less	1	2	3	4	☐
h.	I have sex less often than I would like to	1	2	3	4	☐
i.	I feel different from other people	1	2	3	4	☐
j.	The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k.	I am afraid to have sex	1	2	3	4	☐
l.	I avoid traveling by plane or train	1	2	3	4	☐
m.	I avoid going out to eat	1	2	3	4	☐
n.	Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

Q4. **During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?** (Please tick only one)

- ○ Extremely so – to the point that I have just about given up
- ○ Very much so
- ○ Quite a bit
- ○ Some-enough to bother me
- ○ A little bit
- ○ Not at all

Date: ___ / ___ /

James Cook University

TOWNSVILLE HOSPITAL

PHYSICIAN SURVEY FORM

Faecal Incontinence Research Group

Continence Score (Wexner Scale):

Please mark all 5 rows with a tick as appropriate

Type of incontinence		*Frequency*					
		NEVER	**RARELY** <1/month	**SOMETIMES** <1/week, >1/month	**USUALLY** <1/day, >1/week	**ALWAYS** >1/day	**TOTAL**
❶	Solid	0	1	2	3	4	
❷	Liquid	0	1	2	3	4	
❸	Gas	0	1	2	3	4	
❹	Wears Pad	0	1	2	3	4	
❺	Lifestyle alteration	0	1	2	3	4	
	TOTAL						

Have you ever soiled your underwear with <u>solid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Have you ever soiled your underwear with <u>liquid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Can you control your flatus? ☐ Yes ☐ No

⇨ (If yes) On average how often would you lose control

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you need to wear a pad for <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how frequently do you wear a pad for faecal soiling

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you have to make adjustments in your daily life because of <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how regularly do you have to make such adjustments

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

LABEL

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL

SATISFACTION RATING

Faecal Incontinence Research Group

Q1. **Please can you tell me, on a score out of 10 how satisfied you are with the results of your treatment?**

0 1 2 3 4 5 6 7 8 9 10

0 (unsatisfied) 3 (a little) 6 (moderately) 10 (Extremely)

Q2. **How helpful to you were the following treatment strategies?**

In treating accidental bowel leakage:		**Not helpful**	**A little helpful**	**Very helpful**	**Extremely helpful**
a.	Discussing your problem with the therapist?	1	2	3	4
b.	Learning and using relaxation breathing?	1	2	3	4
c.	Learning and using new coping mechanisms?	1	2	3	4
d.	Learning and using new exercises	1	2	3	4
e.	Seeing how well you have performed the exercises on the computer screen	1	2	3	4
f.	Having access to the home biofeedback device	1	2	3	4

Q3. **On a score out of 10 how would <u>you</u> rate your bowel control prior to this therapy?**

0 1 2 3 4 5 6 7 8 9 10

0 (very, very poor) 5 (OK) 10 (Extremely good)

Q4. **On a score out of 10 how would <u>you</u> rate your bowel control now?**

0 1 2 3 4 5 6 7 8 9 10

0 (very, very poor) 5 (OK) 10 (Extremely good)

In your initial survey you stated that you had been suffering with bowel incontinence for months. May I ask how long did you have this problem before you sought help?

Can you tell me why it took this long?

Who did you seek help from initially?

To whom did they refer you?

What advice would you give to a friend who was experiencing the same problem?

What advice/recommendations would you give to doctors/GPs in their efforts to find out if a patient of theirs may have this problem?

Did you find it hard to bring the problem up with your GP?

Would a confidential survey, completed in the waiting room that you handed straight to the GP help discussion of this and other potentially embarrassing problems?

Would you have considered being a home biofeedback candidate if this was offered (explained home biofeedback)?

Do you think that there is enough FI information available in the community?

We are considering making a video on the biofeedback program to enable support in the rural/remote & non Townsville areas to work with the proposed home biofeedback therapy. Do you think that this could benefit others with a similar problem?

Do you have any questions or feedback?

LABEL

James Cook University

TOWNSVILLE HOSPITAL PATIENT SURVEY

Faecal Incontinence Research Group

Randomized controlled clinical trial of biofeedback in Faecal Incontinence patients

2-Year follow-up survey

1. In general would you say your health is:

   ☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor

2. Do you still perform the pelvic floor muscle and anal sphincter exercises recommended during biofeedback therapy?

   ☐ No ☐ Yes:

   a. How many anal squeezes (back) do you perform a day?

   _____ Rapid _____ Sustained And on how many days a week? _____

   b. How many Pelvic Floor muscle exercises (front) do you perform a day?

   _____ Rapid _____ Sustained And on how many days a week? _____

   ☐ I still know how to perform these exercises

   ☐ I have forgotten how to perform these exercises

3. Have you had any other treatment(s) for bowel leakage since attending the 2005/6 biofeedback therapy?

   ☐ No

   ☐ Yes - what treatment? ☐ Silicone implants ☐ Repeat biofeedback ☐ Physiotherapy ☐ Surgery ☐ Stoma ☐ Other….....

4. Do you believe you need more sessions with the biofeedback therapist?

   ☐ Yes ☐ No

5. How many bowel motions do you usually have each day? _____

LABEL

6. From the Bristol stool form scale below, what type are your stools / bowel motions usually? Type_____

The Bristol Stool Form Scale

Type 1		Separate hard lumps, like nuts (hard to pass)
Type 2		Sausage-shaped, but lumpy
Type 3		Like a sausage but with cracks on the surface
Type 4		Like a sausage or snake, smooth and soft
Type 5		Soft blobs with clear-cut edges (passed easily)
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces, ENTIRELY LIQUID

7. For each of the statements below, please indicate (by circling the relevant number) how much of the time the issue is a concern for you **due to accidental bowel leakage.**

(If it is a concern for you for reasons other than accidental bowel leakage, then tick the box under Not Applicable, (N/A).)

Due to accidental bowel leakage:		**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**	**N/A**
a.	I am afraid to go out	1	2	3	4	☐
b.	I avoid visiting friends	1	2	3	4	☐
c.	I avoid staying overnight away from home	1	2	3	4	☐
d.	It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e.	I cut down on how much I eat before I go out	1	2	3	4	☐
f.	Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g.	It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h.	I avoid travelling	1	2	3	4	☐
i.	I worry about not being able to get to the toilet on time	1	2	3	4	☐
j.	I feel I have no control over my bowels	1	2	3	4	☐
k.	I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l.	I leak stool without even knowing it	1	2	3	4	☐
m.	I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

8. **Due to accidental bowel leakage,** please indicate *(by circling the relevant number)* the extent to which you agree or disagree with each of the following items.

   (If it is a concern for you for reasons other than accidental bowel leakage then tick the box under Not Applicable, (N/A).)

Due to accidental bowel leakage:		**Strongly agree**	**Somewhat agree**	**Somewhat disagree**	**Strongly disagree**	**N/A**
a.	I feel ashamed	1	2	3	4	☐
b.	I can not do many of the things I want to do	1	2	3	4	☐
c.	I worry about bowel accidents	1	2	3	4	☐
d.	I feel depressed	1	2	3	4	☐
e.	I worry about others smelling stool on me	1	2	3	4	☐
f.	I feel like I am not a healthy person	1	2	3	4	☐
g.	I enjoy life less	1	2	3	4	☐
h.	I have sex less often than I would like to	1	2	3	4	☐
i.	I feel different from other people	1	2	3	4	☐
j.	The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k.	I am afraid to have sex	1	2	3	4	☐
l.	I avoid travelling by plane or train	1	2	3	4	☐
m.	I avoid going out to eat	1	2	3	4	☐
n.	Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

9. During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile? (please tick only one)

   ☐ Extremely so – to the point that I have just about given up
   ☐ Very much so
   ☐ Quite a bit
   ☐ Some-enough to bother me
   ☐ A little bit
   ☐ Not at all

10. Have you changed your diet or started taking supplements or medications that have lessened or increased your bowel leakage?

    ☐ No

    ☐ Yes (please describe): ……

    ……

    ……

    ……

    ……

    ……

    ……

11. In the past 12 months have you soiled your clothes or underwear through bowel leakage due to a **reaction to a virus, medication or bad food**? *(Please tick one)*

☐ Never ☐ Once or twice ☐ 3 – 5 times ☐ More than 5 times

12. In the past 12 months and **not due** to a reaction to a virus, medication or bad food, please tick how often you have had accidental bowel leakage and what type?

Type of accidental bowel leakage	Frequency				
	Never	Rarely	Sometimes	Usually	Always
		Less than once per month	More than once per month and less than once per week	More than once per week and less than once per day	Once or more per day
SOLID					
LIQUID					
MUCUS					
GAS (Flatus/Wind)					
Please tick how often you wear a pad to protect your clothes against bowel leakage					
I wear a pad					
Please tick how often you make adjustments to your lifestyle because of:					
Bowel leakage					

13. Has the accidental bowel leakage (described in Q12) been mainly:

☐ Staining ☐ Moderate amount ☐ Large amount ☐ No leakage *(please tick one)*

Please use the space below to provide any comments on your current bowel health:

_____

_____

_____

_____

_____

_____

_____

THANK YOU VERY MUCH FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE AND MAKING A VALUABLE CONTRIBUTION TO OUR RESEARCH.

Please place the completed questionnaire in the stamped addressed envelope provided and mail to us at:

2005/6 Biofeedback Study, Anton Breinl Centre (TTH),
School of Public Health, Tropical Medicine & Rehabilitation Sciences,
James Cook University, Townsville, QLD 4811

LABEL

Queensland Government
Queensland Health

Townsville Health Service District
Institutional Ethics Committee

PATIENT CONSENT FORM

PROTOCOL NAME: **Randomized controlled clinical trial (RCT) of biofeedback in Faecal Incontinence (FI) patients**

INVESTIGATORS: **Lynne Bartlett, Kathryn Sloots, Craig Veitch, Yik Hong Ho**

1. The nature and purpose of the research project has been explained to me. I understand it, and agree to take part.

2. I have been given an Information Sheet which explains the purpose of the study, the possible benefits, and the possible risks.

3. I understand that I may not directly benefit from taking part in the trial.

4. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

5. I understand that I can withdraw from the study at any stage and that it will not affect my medical care, now or in the future.

6 I have had the opportunity to discuss taking part in this investigation with a family member or friend.

NAME OF PATIENT: _____

SIGNED: _____

DATED: _____

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved

SIGNATURE OF INVESTIGATORS: _____

PATIENT INFORMATION SHEET

PROTOCOL NAME: **Randomized controlled clinical trial (RCT) of biofeedback in Faecal Incontinence (FI) patients**

INVESTIGATORS: **Lynne Bartlett, Kathryn Sloots, Craig Veitch, Yik Hong Ho.**

WHAT IS THE PURPOSE OF THIS STUDY?

1. To determine whether an alternative exercise regime improves FI outcomes compared with the standard regime.
2. To determine the effect of a FI information session on the subjective rating of the symptoms of FI and the impact of FI on the quality of life

WHY EVALUATE AN ALTERNATIVE EXERCISE REGIME?

Researchers can only determine how well a new treatment improves patient outcomes by conducting a trial of the new and old treatments and comparing the results.

We greatly appreciate your time and the advice you are give. By assisting with this study you are helping to reduce or even remove the distress others may face through Faecal Incontinence.

WHY EVALUATE WHEN WE MEASURE FI IMPACT AND SEVERITY?

We have found that despite high patient satisfaction with the TTH FI biofeedback program; the survey instruments used to measure impact and severity show inconclusive results prior to and post treatment. We wish to find out if the patient history disclosure has an effect on these measurements.

WHAT ARE WE ASKING OF YOU?

We are asking you to

1. Undertake one of two randomly allocated biofeedback therapies for FI
2. To complete patient surveys prior to the 1st and second session and after the final session.

The existing treatment offered by TTH is a well established method which produces excellent results. The alternative treatment is an extension of the existing treatment and may produce even better results.

PATIENT RANDOMISATION TO EACH THERAPY

Patients who have consented to participate in the study will be randomly allocated to one of the two treatments using a computerized random number generator prior to their second session with the biofeedback therapist. Patients will not know which treatment group they have been allocated to.

WITHDRAWAL FROM THE STUDY

You have the right to withdraw from the study at any time and that your non-participation will not affect your future health care.

FUNDING OF THE STUDY

This study will be funded by a James Cook University School of Public Health and Tropical Medicine grant. The funding will be used to provide the services of:

- A Biofeedback Therapist (one day per week for 44 weeks)
- A research assistant to survey patients and to analyze data (1/2 day per week for 44 weeks)

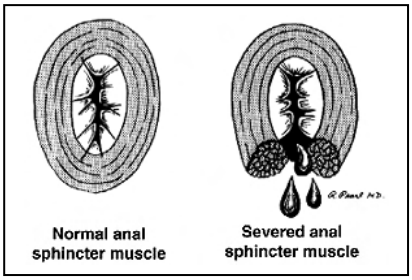
WHAT IS FAECAL INCONTINENCE?

Faecal incontinence is the involuntary loss of liquid or solid stools through the anus with or without the patient's awareness

WHAT CAUSES INCONTINENCE?

There are many causes of incontinence:

- Injuries during childbirth
- Injury to anal muscles
- Anal infections
- Diminished muscle strength with age



WHAT CAN BE DONE TO CORRECT THE PROBLEM?

After a careful history, physical examination and testing to determine the cause and severity of the problem, treatment can be given. This may include:

• Dietary changes	• Biofeedback	• Muscle strengthening exercises
• Constipating medications	• Surgical muscle repair	

INVESTIGATOR CONTACT NAME: *Lynne Bartlett*

INVESTIGATOR CONTACT TELEPHONE NO: *07 4796 1721*

DATED: *4th January 2005*

SIGNATURE OF CONTACT INVESTIGATOR:

ETHICS COMMITTEE CONTACT DETAILS:

Townsville Health Service District Institutional Ethics Committee
The Townsville Hospital
Angus Smith Drive PO Box 670 TOWNSVILLE QLD 4810
DOUGLAS QLD 4814
Phone: 07 4796 1003 Fax: 07 4796 1021

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Queensland Government

Queensland **Health**

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for privacy reasons

Office	Postal	Phone	Fax
The Townsville Hospital Angus Smith Drive DOUGLAS Q 4814	PO Box 670 TOWNSVILLE Q 4810	0011 61 7 4796 1003	0011 61 7 4796 1021

Queensland Government

Queensland **Health**

Content has been removed
for privacy reasons

Office	Postal	Phone	Fax
The Townsville Hospital Angus Smith Drive DOUGLAS Q 4814	PO Box 670 TOWNSVILLE Q 4810	0011 61 7 4796 1003	0011 61 7 4796 1021

Please remember to:

- Contact the unit to confirm your appointments.

  Appointments for biofeedback patients are pre-booked to a strict regime. It is important that you attend all of your appointments as these WILL NOT be rescheduled and may result in discontinuation of your treatment.

- Contact the unit if you have any questions about the procedure or your appointment dates/times.

- Reception office hours are Monday to Friday 8.00am to 4.00pm.

These tests are performed in the Clinical Measurements Unit located in the Surgical Investigations Department, Level 2, The Townsville Hospital.

Surgical Investigations Unit
The Townsville Hospital
PO Box 670
Townsville QLD 4810

Phone: 4796 2712
Fax 4796 2701

Reception Office Hours
Monday – Friday
8.00am to 4.00pm

Queensland Government
Queensland Health

Townsville Health Service District

The Townsville Hospital

ANORECTAL BIOFEEDBACK

Clinical Measurements Unit

Please take the time to read this information sheet as it contains important instructions about how to prepare for the test. Failure to adequately prepare for the test may result in the cancellation of your procedure.

Queensland Government
Queensland Health

Anorectal Biofeedback

What is Anorectal Biofeedback?

The simple exercises you will learn using biofeedback will enable you to become more sensitive to the functioning of your pelvic muscles.

This includes strengthening them to reduce or prevent incontinence, correcting miscoordination of these muscles that may be causing your constipation, and/or learning to simply relax these muscles to eliminate rectal pain.

You may have already been practicing the exercises that are taught during biofeedback, but as these muscles are very difficult to locate, you may not be doing the exercises correctly.

Biofeedback will ensure that you are exercising properly and you will be able to see how well you are improving on the computer screen.

What does the test involve?

Anorectal biofeedback is a series of one-hour sessions each week for four weeks. At the beginning of the course we will do some manometry to get a baseline of how well your anal sphincter is working. In the first week we will concentrate on teaching you how to breathe and relax properly. This is very important, as being able to relax is just as important as being able to exercise and contract muscles properly. This will involve placing a small balloon in your rectum and blowing it up with some air so that you are able to feel it. We will also place a small catheter with a special measuring device on it in your rectum. This will detect any muscle contraction and allow you to see the muscle contraction on a computer screen.

Over the course of the biofeedback sessions we will continue to teach you how to exercise your pelvic floor muscles properly, and how to push properly. At the end of the course, we will repeat the manometry so that we can quantify the improvement in your pelvic floor muscle strength.

Everything will be fully explained to you before and during the procedure and every effort will be made to ensure a minimum of discomfort and a maximum of privacy.

Afterwards

You should have no side effects after the test and will be able to drive and go about your normal day.

NO BOWEL PREPARATION IS REQUIRED FOR THIS TEST

Appendix 4 Home biofeedback randomised control trial documentation

Postcode: _____

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL PATIENT SURVEY

Faecal Incontinence Research Group

Faecal incontinence is an important and often unrecognised problem in the Townsville community. In order to ensure that the best possible services are provided for affected people, the Townsville Hospital and James Cook University are collaborating to determine how many patients are affected and how faecal incontinence impacts on their daily lives. We appreciate you taking the time to complete this questionnaire. It should take no longer than 10-15 minutes to complete.

All information provided will be treated in the strictest confidence.
Should any of the questions be unclear or if you have any questions about this study, please feel free to speak to the person who handed you the questionnaire.
All completed questionnaires should be returned to this research officer.

SECTION 1

1. **Year of Birth** | 1 | 9 | | |

2. **Gender** *(please tick one)* ○ Male ○ Female

3. **If female, how many children have you had by vaginal (not cesarean) delivery?**
_____ (number)

SECTION 2

4. **Do you have any of the following medical conditions?** (tick any that are appropriate)

- ○ Diabetes
- ○ Rectal prolapse
- ○ Chronic constipation requiring prolonged straining to pass a stool
- ○ Psychiatric problems requiring ongoing medication.
  If yes, please state diagnosis _____
- ○ Colon disease. If yes, please state diagnosis _____
- ○ Spinal cord disease. If yes, please state diagnosis _____
- ○ Neurological disease. If yes, please state diagnosis _____
- ○ Urinary incontinence.
  a) If you accidentally soil with urine, how often does it occur?
  ○ Daily ○ Monthly
  ○ Weekly ○ Less often
  b) If you accidentally soil with urine, is there usually:
  ○ Just minimal soiling of your underwear (no need to immediately change underwear)
  ○ Major soiling of your underwear (need to immediately change underwear)
  ○ Soiling of outer clothes
  ○ Soiling of furniture or bedding
- ○ None of the above

LABEL

5. **Have you had any of the following?** (tick any that are appropriate)

- ○ Surgery for haemorrhoids / anal fissures / anal fistulas
- ○ Vaginal repair surgery
- ○ A delivery of a baby requiring a forceps, vacuum, or stitches for a large tear during childbirth (not an episiotomy)
- ○ An injury to the anus
- ○ Radiation therapy. If yes, please state diagnosis _____
- ○ None of the above

6. **Have you consumed any alcohol in the last week?**

- ○ Yes
- ○ No. If no, how long has it been since you last consumed alcohol?____(months) (please proceed to question 8)

7. **If you consumed any alcohol in the last week, please indicate below the type and amount as a total <u>for the whole of last week.</u>**
(If you haven't drunk alcohol in the last week please proceed to **question 8.**).

- ○ Beer _____pots, cans or stubbies
- ○ Spirits _____nips
- ○ Wine _____glasses
- ○ Other, please specify _____

8. **In general would you say your health is:**

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

9. **Do you ever accidentally soil your clothes or underclothes with faeces?** (please tick one)

- ○ No (**<u>If no, you have now finished this survey</u>.** Thank-you very much for participating.)
- ○ Yes (**<u>If yes, please proceed to question</u> 10** below)

SECTION 3

10. **If you have ever accidentally soiled your clothes or underclothes with faeces, how often does this usually happen** (please tick only one)

○ Daily ○ Monthly

○ Weekly ○ Less often

11. **How many months ago did this problem start?** _____(months)

12. **How would you describe the accidental soiling?** (please tick only one)

○ Mainly watery ○ Mainly formed ○ Both

13. **How often do you accidentally soil without being aware of it at first?**

○ Always ○ Sometimes ○ Never

14. **How often do you accidentally soil after you've felt the urge to go to the toilet but weren't able to make it in time?**

○ Always ○ Sometimes ○ Never

15. **Do you usually use some method for controlling accidental soiling?** (tick all that apply)

- ○ No
- ○ A pad
- ○ Anti-diarrhoeal medication
- ○ Other, please specify the method used _____

16. **When you accidentally soil, is there usually:** (please tick only one)

- ○ Just minimal soiling of your underwear (no need to change immediately)
- ○ Major soiling of your underwear (need to immediately change underwear)
- ○ Soiling of outer clothes
- ○ Soiling of furniture or bedding

17. **Do you use any of the following** (tick any that are appropriate)

- ○ Laxatives at least three times each week
- ○ Enemas or suppositories at least three times each week
- ○ Any other object inserted into your anus (including a finger or any other body parts)
- ○ None of the above

SECTION 4

18. **For each of the statements below, please indicate *(by circling the relevant number)* how much of the time the issue is a concern for you DUE TO ACCIDENTAL BOWEL LEAKAGE.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	Most of the time	Some of the time	A little of the time	None of the time	N/A
a.	I am afraid to go out	1	2	3	4	☐
b.	I avoid visiting friends	1	2	3	4	☐
c.	I avoid staying overnight away from home	1	2	3	4	☐
d.	It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e.	I cut down on how much I eat before I go out	1	2	3	4	☐
f.	Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g.	It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h.	I avoid travelling	1	2	3	4	☐
i.	I worry about not being able to get to the toilet on time	1	2	3	4	☐
j.	I feel I have no control over my bowels	1	2	3	4	☐
k.	I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l.	I leak stool without even knowing it	1	2	3	4	☐
m.	I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

19. **<u>DUE TO ACCIDENTAL BOWEL LEAKAGE</u>, please indicate *(by circling the relevant number)* the extent to which you agree or disagree with each of the following items.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

Due to accidental bowel leakage:		Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree	N/A
a.	I feel ashamed	1	2	3	4	☐
b.	I can not do many of the things I want to do	1	2	3	4	☐
c.	I worry about bowel accidents	1	2	3	4	☐
d.	I feel depressed	1	2	3	4	☐
e.	I worry about others smelling stool on me	1	2	3	4	☐
f.	I feel like I am not a healthy person	1	2	3	4	☐
g.	I enjoy life less	1	2	3	4	☐
h.	I have sex less often than I would like to	1	2	3	4	☐
i.	I feel different from other people	1	2	3	4	☐
j.	The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k.	I am afraid to have sex	1	2	3	4	☐
l.	I avoid travelling by plane or train	1	2	3	4	☐
m.	I avoid going out to eat	1	2	3	4	☐
n.	Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

20. **During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?** (please tick only one)

- ○ Extremely so – to the point that I have just about given up
- ○ Very much so
- ○ Quite a bit
- ○ Some-enough to bother me
- ○ A little bit
- ○ Not at all

THANK YOU FOR YOUR TIME.

PLEASE RETURN YOUR COMPLETED QUESTIONNAIRE TO THE RESEARCH OFFICER.

The JCU Faecal Incontinence Research Group:

- Prof. Yik-Hong Ho, Townsville Hospital, phone: 4796 1417
- Prof. Craig Veitch, School of Medicine, phone: 4781 6408
- Lynne Bartlett, School of Public Health, phone: 4796 1721

Date: ___ / ___ /

James Cook University

TOWNSVILLE HOSPITAL

PHYSICIAN SURVEY FORM

Faecal Incontinence Research Group

Continence Score (Wexner Scale):

Please mark all 5 rows with a tick as appropriate

Type of incontinence		*Frequency*					
		NEVER	**RARELY** <1/month	**SOMETIMES** <1/week, >1/month	**USUALLY** <1/day, >1/week	**ALWAYS** >1/day	**TOTAL**
❶	Solid	0	1	2	3	4	
❷	Liquid	0	1	2	3	4	
❸	Gas	0	1	2	3	4	
❹	Wears Pad	0	1	2	3	4	
❺	Lifestyle alteration	0	1	2	3	4	
	TOTAL						

Have you ever soiled your underwear with <u>solid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Have you ever soiled your underwear with <u>liquid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Can you control your flatus? ☐ Yes ☐ No

⇨ (If yes) On average how often would you lose control

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you need to wear a pad for <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how frequently do you wear a pad for faecal soiling

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you have to make adjustments in your daily life because of <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how regularly do you have to make such adjustments

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

LABEL

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL PATIENT SURVEY

Faecal Incontinence Research Group

Q1. **In general would you say your health is?**

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

Q2. For each of the statements below, please indicate *(by circling the relevant number)* how much of the time the issue is a concern for you **due to accidental bowel leakage.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**	**N/A**
a.	I am afraid to go out	1	2	3	4	☐
b.	I avoid visiting friends	1	2	3	4	☐
c.	I avoid staying overnight away from home	1	2	3	4	☐
d.	It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e.	I cut down on how much I eat before I go out	1	2	3	4	☐
f.	Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g.	It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h.	I avoid travelling	1	2	3	4	☐
i.	I worry about not being able to get to the toilet on time	1	2	3	4	☐
j.	I feel I have no control over my bowels	1	2	3	4	☐
k.	I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l.	I leak stool without even knowing it	1	2	3	4	☐
m.	I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

LABEL

Please turn over page

Q3. **DUE TO ACCIDENTAL BOWEL LEAKAGE, please indicate *(by circling the relevant number)* the extent to which you agree or disagree with each of the following items.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree	N/A
a.	I feel ashamed	1	2	3	4	☐
b.	I can not do many of the things I want to do	1	2	3	4	☐
c.	I worry about bowel accidents	1	2	3	4	☐
d.	I feel depressed	1	2	3	4	☐
e.	I worry about others smelling stool on me	1	2	3	4	☐
f.	I feel like I am not a healthy person	1	2	3	4	☐
g.	I enjoy life less	1	2	3	4	☐
h.	I have sex less often than I would like to	1	2	3	4	☐
i.	I feel different from other people	1	2	3	4	☐
j.	The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k.	I am afraid to have sex	1	2	3	4	☐
l.	I avoid traveling by plane or train	1	2	3	4	☐
m.	I avoid going out to eat	1	2	3	4	☐
n.	Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

Q4. **During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?** (Please tick only one)

- ○ Extremely so – to the point that I have just about given up
- ○ Very much so
- ○ Quite a bit
- ○ Some-enough to bother me
- ○ A little bit
- ○ Not at all

Date: ___ / ___ /

James Cook University

TOWNSVILLE HOSPITAL

PHYSICIAN SURVEY FORM

Faecal Incontinence Research Group

Continence Score (Wexner Scale):

Please mark all 5 rows with a tick as appropriate

Type of incontinence		*Frequency*					
		NEVER	**RARELY** <1/month	**SOMETIMES** <1/week, >1/month	**USUALLY** <1/day, >1/week	**ALWAYS** >1/day	**TOTAL**
❶	Solid	0	1	2	3	4	
❷	Liquid	0	1	2	3	4	
❸	Gas	0	1	2	3	4	
❹	Wears Pad	0	1	2	3	4	
❺	Lifestyle alteration	0	1	2	3	4	
	TOTAL						

Have you ever soiled your underwear with <u>solid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Have you ever soiled your underwear with <u>liquid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Can you control your flatus? ☐ Yes ☐ No

⇨ (If yes) On average how often would you lose control

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you need to wear a pad for <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how frequently do you wear a pad for faecal soiling

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you have to make adjustments in your daily life because of <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how regularly do you have to make such adjustments

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

LABEL

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL PATIENT SURVEY

Faecal Incontinence Research Group

Q1. **In general would you say your health is?**

○ Excellent ○ Very good ○ Good ○ Fair ○ Poor

Q2. For each of the statements below, please indicate *(by circling the relevant number)* how much of the time the issue is a concern for you **due to accidental bowel leakage.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**	**N/A**
a.	I am afraid to go out	1	2	3	4	☐
b.	I avoid visiting friends	1	2	3	4	☐
c.	I avoid staying overnight away from home	1	2	3	4	☐
d.	It is difficult for me to get out and do things like going to a movie or to church	1	2	3	4	☐
e.	I cut down on how much I eat before I go out	1	2	3	4	☐
f.	Whenever I am away from home, I try to stay near a restroom as much as possible	1	2	3	4	☐
g.	It is important to plan my schedule (daily activities) around my bowel pattern	1	2	3	4	☐
h.	I avoid travelling	1	2	3	4	☐
i.	I worry about not being able to get to the toilet on time	1	2	3	4	☐
j.	I feel I have no control over my bowels	1	2	3	4	☐
k.	I can't hold my bowel movement long enough to get to the bathroom	1	2	3	4	☐
l.	I leak stool without even knowing it	1	2	3	4	☐
m.	I try to prevent bowel accidents by staying very near a bathroom	1	2	3	4	☐

LABEL

Please turn over page

Q3. **DUE TO ACCIDENTAL BOWEL LEAKAGE, please indicate *(by circling the relevant number)* the extent to which you agree or disagree with each of the following items.** (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Applicable, (N/A).)

	Due to accidental bowel leakage:	**Strongly agree**	**Somewhat agree**	**Somewhat disagree**	**Strongly disagree**	**N/A**
a.	I feel ashamed	1	2	3	4	☐
b.	I can not do many of the things I want to do	1	2	3	4	☐
c.	I worry about bowel accidents	1	2	3	4	☐
d.	I feel depressed	1	2	3	4	☐
e.	I worry about others smelling stool on me	1	2	3	4	☐
f.	I feel like I am not a healthy person	1	2	3	4	☐
g.	I enjoy life less	1	2	3	4	☐
h.	I have sex less often than I would like to	1	2	3	4	☐
i.	I feel different from other people	1	2	3	4	☐
j.	The possibility of bowel accidents is always on my mind	1	2	3	4	☐
k.	I am afraid to have sex	1	2	3	4	☐
l.	I avoid traveling by plane or train	1	2	3	4	☐
m.	I avoid going out to eat	1	2	3	4	☐
n.	Whenever I go someplace new, I specifically locate where the bathrooms are	1	2	3	4	☐

Q4. **During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?** (Please tick only one)

- ○ Extremely so – to the point that I have just about given up
- ○ Very much so
- ○ Quite a bit
- ○ Some-enough to bother me
- ○ A little bit
- ○ Not at all

Date: ___ / ___ /

James Cook University

TOWNSVILLE HOSPITAL

PHYSICIAN SURVEY FORM

Faecal Incontinence Research Group

Continence Score (Wexner Scale):

Please mark all 5 rows with a tick as appropriate

Type of incontinence		*Frequency*					
		NEVER	**RARELY** <1/month	**SOMETIMES** <1/week, >1/month	**USUALLY** <1/day, >1/week	**ALWAYS** >1/day	**TOTAL**
❶	Solid	0	1	2	3	4	
❷	Liquid	0	1	2	3	4	
❸	Gas	0	1	2	3	4	
❹	Wears Pad	0	1	2	3	4	
❺	Lifestyle alteration	0	1	2	3	4	
	TOTAL						

Have you ever soiled your underwear with <u>solid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Have you ever soiled your underwear with <u>liquid faeces</u>? ☐ Yes ☐ No

⇨ (If yes) On average how often would this occur

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Can you control your flatus? ☐ Yes ☐ No

⇨ (If yes) On average how often would you lose control

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you need to wear a pad for <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how frequently do you wear a pad for faecal soiling

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

= = = = = = = = = = = = = = = = = = =

Do you have to make adjustments in your daily life because of <u>faecal incontinence</u>? ☐ Yes ☐ No

⇨ (If yes) , how regularly do you have to make such adjustments

⇨ ☐ < 1/month ☐ 1/week - 1/month ☐ 1/day – 1/week ☐ >1/day

LABEL

Date: ___ / ___ / ___

James Cook University

TOWNSVILLE HOSPITAL

SATISFACTION RATING

Faecal Incontinence Research Group

Q1. **Please can you tell me, on a score out of 10 how satisfied you are with the results of your treatment?**

0 1 2 3 4 5 6 7 8 9 10

0 (unsatisfied) 3 (a little) 6 (moderately) 10 (Extremely)

Q2. **How helpful to you were the following treatment strategies?**

In treating accidental bowel leakage:		**Not helpful**	**A little helpful**	**Very helpful**	**Extremely helpful**
a.	Discussing your problem with the therapist?	1	2	3	4
b.	Learning and using relaxation breathing?	1	2	3	4
c.	Learning and using new coping mechanisms?	1	2	3	4
d.	Learning and using new exercises	1	2	3	4
e.	Seeing how well you have performed the exercises on the computer screen	1	2	3	4
f.	Having access to the home biofeedback device	1	2	3	4

Q3. **On a score out of 10 how would <u>you</u> rate your bowel control prior to this therapy?**

0 1 2 3 4 5 6 7 8 9 10

0 (very, very poor) 5 (OK) 10 (Extremely good)

Q4. **On a score out of 10 how would <u>you</u> rate your bowel control now?**

0 1 2 3 4 5 6 7 8 9 10

0 (very, very poor) 5 (OK) 10 (Extremely good)

In your initial survey you stated that you had been suffering with bowel incontinence for months. May I ask how long did you have this problem before you sought help?

Can you tell me why it took this long?

Who did you seek help from initially?

To whom did they refer you?

What advice would you give to a friend who was experiencing the same problem?

What advice/recommendations would you give to doctors/GPs in their efforts to find out if a patient of theirs may have this problem?

Did you find it hard to bring the problem up with your GP?

Would a confidential survey, completed in the waiting room that you handed straight to the GP help discussion of this and other potentially embarrassing problems?

Use of Peritrons

1. How convenient was the peritron to use?
2. Did you find the peritron helped with your exercises?
3. How many times did you use it before muscle awareness and your confidence increased to be able not to use it?
4. Were the numbers easy to interpret? Y / N
    a. Would it be better with bars? Y / N
    b. Would it be better with the sound on Y / N
5. Did you have any problems cleaning / maintaining the peritron?
6. In hindsight would you have agreed to use the peritron if this wasn't a study?
7. Would you use it if available long term?

8. Are you more confident with your exercises since you have been using it?

9. Did the sensation of using it change between the beginning and now?

10. Did you get used to inserting the sensor?

11. Did the benefits outweigh the inconvenience/discomfort of the peritron?

12. How confident of doing the exercises would you have felt without the peritron?

13. If there was a DVD course & peritron available locally, would you be happy with your local GP/Practice nurse or physiotherapist overseeing the therapy?

    a. Yes

    b. No

    c. Yes – but with support from specialist clinic

14. Was it a positive experience?

Do you think that there is enough FI information available in the community?

Do you have any questions or feedback?

LABEL

PARTICIPANT INFORMATION FORM

Version 1 Dated 13th February 2006

Site: School of Public Health, Tropical Medicine & Rehabilitation Sciences
James Cook University

Full Project Title: **An investigation to determine whether the biofeedback controlled exercise regimen using home biofeedback devices provides better outcomes than the standard clinic biofeedback regimen.**

Principal Researcher: Lynne Bartlett

Associate Researchers: Kathryn Sloots, Prof Yik-Hong Ho, Prof Richard Speare, Dr Madeleine Nowak

This Participant Information Form is 4 pages long. Please make sure you have all the pages.

1. Your consent

You are invited to take part in this research project.

The Participant Information contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in the project before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may wish to discuss the project with a relative or friend or your local health worker. Feel free to do this.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. Purpose and Background

Biofeedback is a safe, conservative, first-line therapy with no known side effects for patients with mild to moderate FI who have not responded to simple dietary advice or medication. The Townsville Hospital currently operates a Biofeedback clinic for FI, constipation and related pain one day per week in the Clinical Measurements Unit. This study will provide a second “JCU Study” clinic.
The purpose of the study is to determine whether the use of hand-held biofeedback devices during daily pelvic floor and anal squeeze exercises improves severity outcomes by 20% in patients with faecal incontinence.

3. Procedures

Participants will:

a. be interviewed and complete a questionnaire prior to their first session
b. receive anorectal manometry conducted on the hospital equipment and will have relevant history taken and learn a relaxation breathing technique during session 1
c. be randomly assigned to the standard treatment or home biofeedback group
d. in sessions 2 and 3 learn the exercise regime. Participants in the home biofeedback group will, after signing an agreement to return it, be loaned a Peritron and will be taught how to use it. Data from Week 2 will be uploaded during session 3
e. undertake 4 weeks of home practice. Home biofeedback group will be asked to use the device for exercise practice at least once per day
f. have anorectal manometry conducted on the hospital equipment during session 4. Participants in the home biofeedback group will have data from weeks 3-7 uploaded during session 4.
g. Complete a questionnaire and participate in an in depth interview after session 4.

Home biofeedback participants will undergo their clinic biofeedback therapy using the home biofeedback machines.

All participants will be encouraged to practice their exercises at home.

4. Possible Benefits

The second “JCU Study” clinic will enable many patients to receive therapy much sooner than the .current waiting time. Patients randomized onto the home biofeedback group will have the opportunity to view and improve their daily exercise performance.

5. Possible Risks

Handling of the home biofeedback device anal probes may enable transfer of faecal matter:

Each home biofeedback group participant will receive a sterilized connecting tube and anal probe with their loaned Peritron at session 2. Immediately after use, home biofeedback patients will need to wash the probe and connecting tube in warm soapy water and rinse in clean water and dry.

6. Alternatives to Participation

FI Patients who do not wish to participate in the study may wait for a place on the Clinical Measurements Unit waitlist that includes FI, constipation and pelvic pain patients.

7. Privacy, Confidentiality and Disclosure of Information

All information collected from you is treated as strictly confidential and will only be used by researchers involved in the project.

- All questionnaires and data are stored securely and labeled with a numerical code so that they cannot be immediately identified as having come from you.
- Any identifying information (your full name, address etc) will be stored separately from the information you provide. Access to this identifying information is restricted to a small number of the study team.
- No information that could be used to identify you or your family will be included in any report or publication on the results of this project. If you give us your permission by signing the Consent Form, we plan to publish the results with international peer reviewed journals. In addition only grouped results will be used in reports or publications.
- Your information will be stored for 15 years because it could be useful for as yet unspecified future research. No other research would be undertaken without your consent unless required by law.
- You can ask to have your information destroyed at any time.

8. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

9. Results of the Project

All participants will be sent a letter with a summary of the outcomes of the project in the form of group data.

10. Further Information or Any Problems

If you require further information, or if you have any problems concerning this project (for example, any side effects), you can contact the principal researcher or the research nurse.

The researchers for this project are:

- Principal Researcher Lynne Bartlett (07) 4796 1721 After hours 0407 133 692
- Research Nurse Kathryn Sloots (07) 4796 2715
- Associate Researcher Prof Yik-Hong Ho (07) 4796 1417
- Associate Researcher Prof Richard Speare (07) 4781 5959
- Associate Researcher Dr Madeleine Nowak (07) 4796 1748

11. Other Issues

Should you wish to discuss the study with someone not directly involved, in particular in relation to matters concerning policies, information about conduct of the study or your rights as a participant, or should you wish to make an independent complaint, you can contact:

Name: Shannon Campbell
Position: Ethics Administrator
Townsville Health Service District Institutional Ethics Committee
Telephone: (07) 4796 1226

You will need to tell Shannon the name of one of the researchers given in section 10 above.

12. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with James Cook University.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

13. Ethical Guidelines

This study will be carried out according to the National Statement of Ethical Conduct in Research Involving Humans (June 1999) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of the Townsville District Health Service Ethics Committee and the James Cook University Human Ethics Sub-Committee.

14. Reimbursement for your costs

You will **not** be paid for your participation in this project.

JAMES COOK UNIVERSITY
TOWNSVILLE Queensland 4811 Australia Telephone: (07) 4781 4111

PARTICIPANT CONSENT FORM

Version 2 Dated 27th April 2006

PRINCIPAL INVESTIGATOR	*Lynne Bartlett*
PROJECT TITLE	*A randomised study to evaluate the effects of supplementary home biofeedback guided pelvic floor and anal squeeze exercises in the treatment of faecal incontinence to reduce bowel leakage and improve patient quality of life.*
JCU SCHOOL	*School of Public Health, Tropical Medicine & Rehabilitation Sciences*
CONTACT DETAILS	*Lynne Bartlett, Ph: 07 4796 1721, Fax: 07 4796 1767, Email: lynne.bartlett@jcu.edu.au*
SITE	*Clinical Measurements, The Townsville Hospital*

I have read, and I understand the Participant Information version 2 dated 22 February 2006.

I freely agree to participate in this project according to the conditions in the Participant Information.

I will be given a copy of the Participant Information and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details if information about this project is published or presented in any public form.

Participant's Name (printed) ……

Signature Date

Name of Witness to Participant's Signature (printed) ……

Signature Date

I confirm that, to the best of my knowledge, the participant has understood the information provided to him/her, the implications of this information and that the participant will be provided with a copy of this document.

Researcher's Name (printed) ……..

Signature Date

Note: All parties signing the Consent Form must date their own signature.

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Townsville Hospital and Health Service
Human Research Ethics Committee
Telephone +617 4433 1140
Email TSV-Ethics-Committee@health.qld.gov.au

Home Biofeedback Study – Peritron Operating instructions

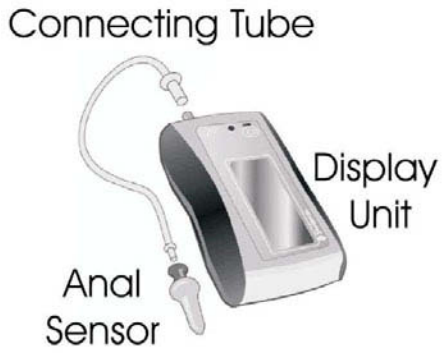

Fig.A

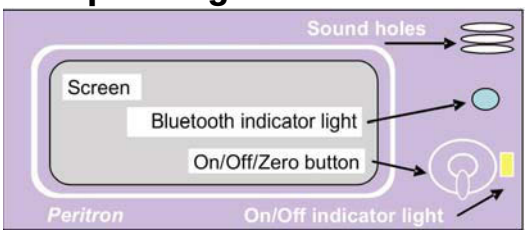

Fig B

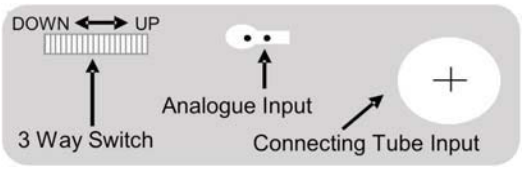

Fig. C

Connecting the Peritron

1. Important – clean **anal sensor** in warm soapy water and dry prior to first use (**with tube connected)**
   ……. *DO NOT WASH DISPLAY UNIT*…….
2. Push one end of connecting-tube into the white base of the blue anal sensor while holding the white base and connect the other into the Display Unit **(**see Figure C)
3. Place a latex finger cot (mini-condom) fully over blue anal sensor

Procedure

1. Turn Display Unit on by clicking **[On/Off/Zero]** button once (see figure B).
2. Insert anal sensor into anus (a tiny amount of lubricant on the end may be used)
3. Zero display by clicking On/Off/Zero Button once…….. [bar on screen flashes]
4. Lightly press three-way-switch down *(away from connecting tube input – see figure C)*. The **screen will display SAVE**. ……[memory light flashes]
5. Perform exercises as prescribed by the research nurse
6. On completion of the exercises press three-way-switch down *(away from connecting tube input – see figure C)*. The **screen will display END**. Switch off: Press/hold **[On/Off/Zero]** button
7. Remove anal sensor when exercise/assessment session is completed.
8. Remove connecting tube from display unit.
9. Remove latex finger cot (mini-condom) from anal sensor and discard.
10. Wash **sensor with connected tube** in warm soapy water immediately, rinse, dry with paper towel.
    ……. *DO NOT WASH DISPLAY UNIT*…….

Anal Squeezes (BACK)

Rapid squeezes with 1 second rest between each squeeze	10 second rest	Sustained squeeze at half strength. Release with control	10 second rest	Sustained squeeze at half strength. Release with control	10 second rest	Sustained squeeze at half strength. Release with control	10 second rest	Maximum squeeze (if prescribed) Sustained squeeze at half strength for 2 seconds, rising to full strength for remainder of prescribed time. Release with control

Pelvic Floor Exercise (FRONT)

Rapid squeezes with 1 second rest between each squeeze	10 second rest	Sustained squeeze at half strength. Release with control	10 second rest	Sustained squeeze at half strength. Release with control	10 second rest	Sustained squeeze at half strength. Release with control	10 second rest	Maximum squeeze (if prescribed) Sustained squeeze at half strength for 2 seconds, rising to full strength for remainder of prescribed time. Release with control

If any other words are displayed on the Peritron, press the three way switch **in** for 2 seconds then start again from 4

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