

RESEARCH ARTICLE

Modified Pilates as an adjunct to standard physiotherapy care for urinary incontinence: a mixed-methods pilot for a randomized controlled trial

A. Lausen

Department of Affective Neuroscience and Psychophysiology, Institute for Psychology, University of Göttingen, Göttingen, Germany, and Department of Mathematical Sciences, University of Essex, Colchester, UK

L. Marsland

School of Health and Social Care, University of Essex, Colchester, UK

S. Head

Physiotherapy Department, Anglian Community Enterprise (ACE) Community Interest Company, Colchester, UK

J. Jackson

School of Sport, Rehabilitation and Exercise Sciences, University of Essex, Colchester, UK

B. Lausen

Department of Mathematical Sciences, University of Essex, Colchester, UK

Abstract

Background. Urinary incontinence (UI) is a distressing condition affecting at least 5 million women in England and Wales. Traditionally, physiotherapy for UI comprises pelvic floor muscle training, but although evidence suggests this can be effective, it is also recognized that benefits are often compromised by patient motivation and commitment. In addition, there is increasing recognition that physical symptoms alone are poor indicators of the impact of incontinence on individuals' lives. Consequently, more holistic approaches to the treatment of UI, such as modified Pilates (MP) have been recommended. This study aimed to provide preliminary findings about the effectiveness of a 6-week course of MP classes as an adjunct to standard physiotherapy care for UI, and to test the feasibility of a randomized controlled trial (RCT) design.

Methods. The study design was a single-centre, pilot RCT, plus qualitative interviews. Seventy-three women referred to Women's Health Physiotherapy Services for UI at Colchester Hospital University NHS Foundation Trust were randomly assigned to two groups: a 6-week course of MP classes in addition to standard physiotherapy care (intervention), or standard physiotherapy care only (control). The main outcome measures were self-reported UI, quality of life, and self-esteem at baseline (T1), completion of treatment (T2) and 5 months after randomization (T3). Qualitative interviews were conducted with a subgroup at T2 and T3. Because of the nature of the intervention, blinding of the participants, physiotherapists and researchers was not feasible.

Results. Post-intervention data revealed a range of benefits for women who attended MP classes, and who had lower symptom severity at baseline: improved self-esteem ($P=0.032$); decreased social embarrassment ($P=0.026$); and lower impact on normal daily activities ($P=0.025$). In contrast, women with higher symptom severity showed improvement in their personal relationships ($P=0.017$). Qualitative analysis supported these findings, and also indicated that MP classes could positively influence attitudes to exercise, diet and well-being.

Conclusions. A definitive RCT is feasible, but will require a large sample size to inform clinical practice.

Trial registration. ISRCTN74075972 (www.isrctn.com/ISRCTN74075972). Registered 12 December 2012 (retrospectively registered).

Electronic supplementary material. The online version of this article (10.1186/s12905-017-0503-y) contains supplementary material, which is available to authorized users.

Keywords: mixed methods, modified Pilates, pelvic floor muscle training, physiotherapy, randomized controlled trial, urinary incontinence.

Background

Urinary incontinence (UI) is a distressing, socially embarrassing condition affecting at least 5 million women in England and Wales (NICE 2013). Feelings of low self-esteem, embarrassment and helplessness are commonly reported (Sinclair & Ramsay 2011), together with withdrawal from social situations (Hunskaar & Vinsnes 1991; NICE 2006). In addition, UI is an important barrier to regular physical and fitness activities (Brown & Miller 2001; Monz *et al.* 2005; Nygaard *et al.* 2005), and this withdrawal may threaten women's general health and well-being (Bø & Sherburn 2005). It is estimated that ill health attributable to physical inactivity costs the National Health Service (NHS) more than £1.06 billion per year, and accounts for 16.9% of premature mortality in the UK (Lee *et al.* 2012). The socioeconomic costs of UI are likely to extend beyond the immediate symptoms, and may escalate as life expectancy increases (Patel *et al.* 2008).

Physiotherapy is important first-line management for UI; many women wish to avoid invasive surgical procedures, if possible, plus physiotherapy may provide a cheaper treatment solution for the NHS. The traditional form of physiotherapy for UI is pelvic floor muscle (PFM) training (PFMT) (CSP 2003; Savage 2005; Culligan *et al.* 2010; NICE 2013; Dumoulin *et al.* 2014). Although a variety of randomized controlled trials (RCTs) have documented the positive effects of intensive PMFT (Culligan *et al.* 2010), it has also been suggested that patient motivation and commitment play an important role in ensuring its effectiveness (Demain *et al.* 2001). Also, there is increasing recognition that symptoms alone are poor indicators of the effect of incontinence on individuals' lives (Tooze-Hobson & Loane 2008). Therefore, more holistic approaches to the treatment of UI have been recommended (Lee & Lee 2004; Tooze-Hobson & Loane 2008).

As an addition to standard UI treatment, more recently Modified Pilates (MP) – a mind–body approach involving slow, controlled movements focusing on posture and breathing – appears to have been increasingly integrated into physiotherapy rehabilitation programmes (Kloubec 2011). Pilates is a form of exercise involving a range of movements that both strengthen and increase flexibility of the whole body, rather than having a specific muscle focus. Modified Pilates avoids intense abdominal contractions, breath-holding or straining that could put increased pressure on the pelvic floor while, at the same time, incorporating exercises that can incidentally train the pelvic floor (Bø & Herbert 2013). However, the effectiveness of this approach is purely anecdotal, with a lack of empirical evidence (Anderson & Spector 2000). A recent systematic review of RCTs identified only two other studies, which aimed to assess the effectiveness of Pilates training in women suffering from UI (Bø & Herbert 2013). Both these studies, however, focused on Pilates provided individually (as opposed to in class sessions), and neither provided sufficient data to permit inferences about the effects of MP (Savage 2005; Culligan *et al.* 2010).

It was apparent, therefore, that a trial to evaluate the effectiveness of a course of MP classes as an adjunct to standard physiotherapy care for UI with an initial pilot study was required. Specifically, this pilot study aimed to: (1) assess the feasibility of the trial protocol to evaluate the effectiveness of a course of MP classes as an adjunct to standard physiotherapy care for UI; (2) assess the variation of the main outcome measures in order to inform sample size considerations for a full RCT; (3) provide some preliminary data about the effectiveness of MP classes; and (4) identify the benefits/limitations and acceptability of standard physiotherapy care plus MP classes compared to standard physiotherapy care alone. To the best of our knowledge, this research is the first to fully evaluate

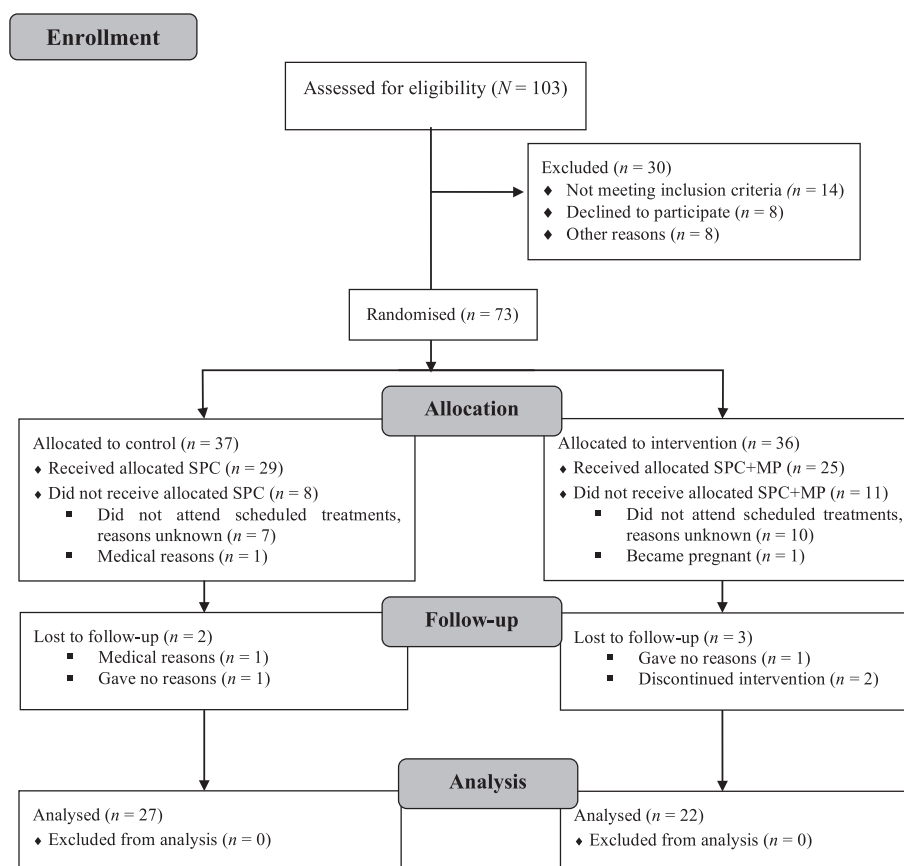


Figure 1. Flowchart of study participants (study period: November 2012–October 2014).

and report on the effectiveness of MP classes as part of the physiotherapy management of women with UI.

Method

Participants

One hundred and three women referred for physiotherapy for UI by their general practitioner, consultant or continence nurse were assessed for eligibility to participate in the trial. The inclusion criteria for taking part in the study were to be aged above 18 years and diagnosed with stress, urge or mixed UI. Participants were not eligible to participate if they had a history of pelvic malignancy, were suffering from faecal incontinence or central nervous system diseases, had given birth in the previous 3 months, or undergone gynaecological surgery in the previous 6 months. Thirty women were excluded or withdrew before randomization (14 did not meet the inclusion criteria, eight declined to participate, and eight withdrew, citing lack of time or other reasons). A total of 73 women [mean age (M_{age}) = 50.11 years, standard deviation (SD) = 13.18 years] were randomly allocated to an intervention or a control group. The control group ($n = 37$, $M_{\text{age}} = 48.97$ years,

SD = 12.25 years) received standard physiotherapy care (SPC) only (i.e. pelvic floor exercises and lifestyle advice), whereas the intervention group ($n = 36$, $M_{\text{age}} = 51.28$ years, SD = 14.15 years) attended a 6-week course of MP classes in addition to SPC (SPC + MP). Figure 1 shows the study's flow diagram according to Consolidated Standards of Reporting Trials guidelines.

Outcome measures

As this was a pilot study, it was appropriate to explore a range of outcome measures (aims 1, 2 and 3). Accordingly, several standardized self-report measures were used to assess participants' symptoms of incontinence [Symptom Severity Index (SSI); Black *et al.* 1996], and their impact on quality of life [Incontinence Quality of Life Questionnaire (I-QOL); Patrick *et al.* 1999; International Consultation on Incontinence Questionnaire – Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol); Kelleher *et al.* 1997; Avery *et al.* 2004] and self-esteem [Rosenberg Self-Esteem Scale (RSES); Rosenberg 1965]. These measures were used in preference to clinical measures such as pad tests or pelvic muscle strength because the focus of this study was the psychological and

social impact of UI on women's lives rather than level of incontinence alone. Furthermore, the project public and patient involvement (PPI) group advised against the burden of including such clinical measures. The PPI group comprised women who had been previously treated for UI, and who provided advice throughout the project to ensure that the research was informed by their views and experiences. Both the intervention and control groups completed the questionnaires at baseline (T1), the end of treatment (T2) and 5 months after randomization (T3). For a brief scoring description of the questionnaires, see "Outcome measures" (in additional file 1: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5767028/bin/12905_2017_503_MOESM1_ESM.docx).

In addition, qualitative interviews were conducted with a subgroup of 16 participants (eight SPC and eight SPC+MP) at T2 and T3 to explore unanticipated benefits/limitations and acceptability of SPC+MP compared with SPC (aim 4). The interviews were undertaken by a qualitative researcher, and were semi-structured in nature, using a topic guide to ensure that all topics were covered with every participant, but allowing varying levels of detail to emerge according to their particular responses. Interviews at T2 lasted between 45 min and 1 h, while those at T3 tended to be shorter, averaging around 30 min.

Design

A single-centre, pilot RCT carried out over 24 months, plus qualitative interviews with a subgroup of participants.

Randomization

Prior to randomization, stratification by body mass index (BMI) and SSI was undertaken since BMI and SSI are known predictors for the successful treatment of UI in women (Subak *et al.* 2005; Danforth *et al.* 2006). Randomization was by computer allocation using the web-based randomization service of the Norwich Clinical Trials Unit. To ensure the treatment groups were similar, a stratified randomization with three strata (i.e. low SSI, high SSI/low BMI and high SSI/high BMI) was used. In each stratum, balanced blocks of random length (four, six or eight) were fitted to assign an equal number of SPC+MP and SPC participants. Because of the nature of the intervention, blinding of participants, physiotherapists and researchers was not feasible.

Setting

The research was conducted at the Women's Health Physiotherapy Service, Colchester Hospital University NHS Foundation Trust (CHUFT).

Procedure

Participants were invited to take part in the study, in which they would undertake either SPC or SPC+MP offered by the Women's Health Physiotherapy Service at CHUFT. The study was approved by the National Research Ethics Service (NRES) East of England Hertfordshire Ethics Committee.

After being screened by the chief investigator or project administrator (PA) for eligibility to take part in the study, the PA telephoned the women to arrange their first clinical appointment. During this call, the PA explained that, together with confirmation of their appointment, they would also be sent details about the research and the participant information sheet. A telephone number, e-mail address and reply slip with pre-paid envelope were provided for those seeking additional information about the research, and/or to indicate interest in participation. Those women who agreed to take part provided written informed consent during their first clinical appointment (SPC session 1). Consented participants then met with the research physiotherapist for assessment of their ability to contract PFMs (through vaginal digital palpation), and to establish whether they had sufficient mental capacity to complete the questionnaires and/or follow exercise instructions (according to the principles of the Mental Capacity Act 2005; DH 2005). The T1 data were collected by the research physiotherapist at the SPC session 2. The T2 and T3 data were collected via questionnaire packs sent by post enclosing a stamped addressed envelope for their return.

The SPC treatment for UI provided by CHUFT Women's Health Physiotherapy Service comprised three to six individual sessions over a 3–6-month period. The National Institute for Health and Care Excellence (NICE) guidelines for UI recommend supervised PFMT of at least 3 months' duration. If PFM contraction has been confirmed, then women are normally offered this supervision via three appointments over the time period (NICE 2013). The SPC sessions included PFMT, biofeedback, a home exercise programme and lifestyle advice. Participants allocated to the SPC+MP intervention received three SPC sessions ahead of the MP classes, with further (up

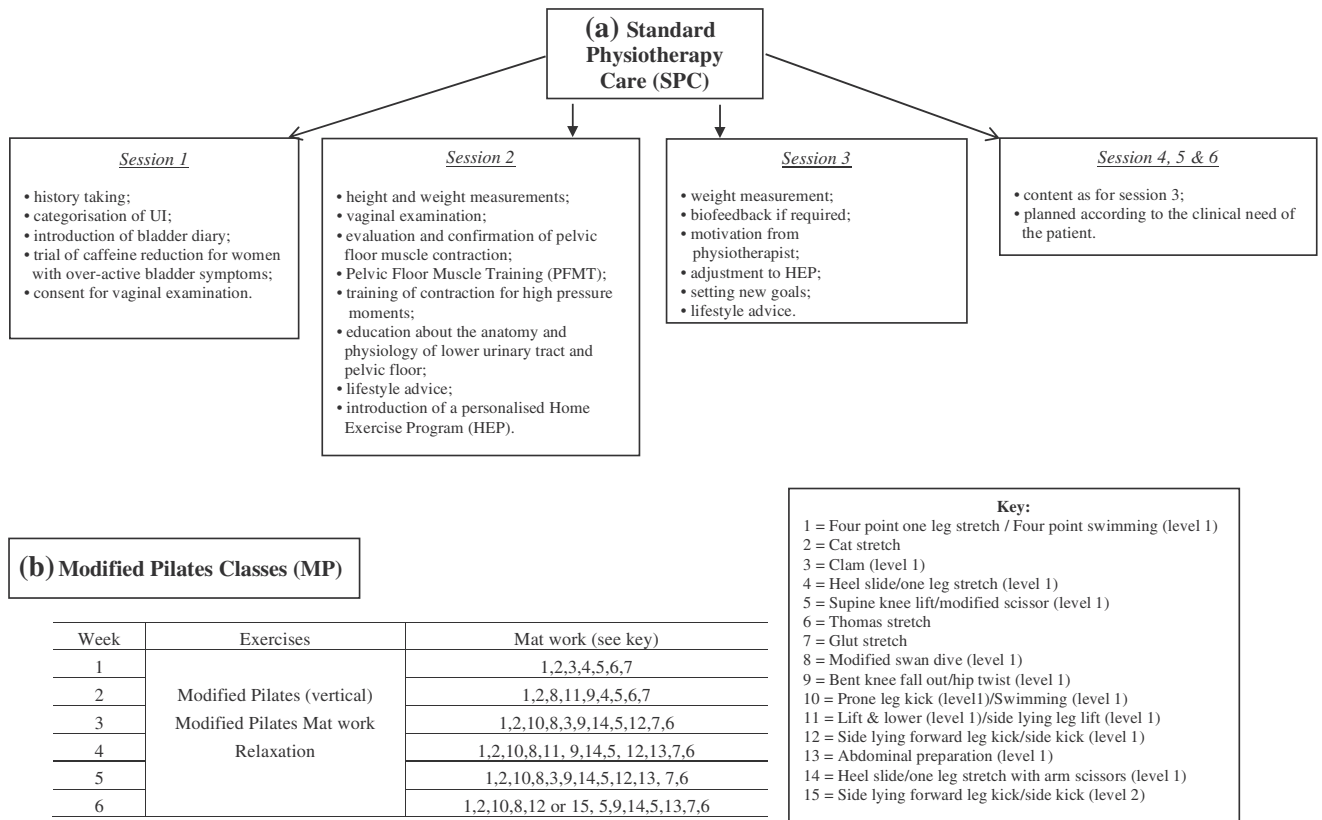


Figure 2. Overviews of (a) the standard physiotherapy care (SPC) sessions, and (b) the modified Pilates (MP) classes.

to a total of six) SPC sessions arranged during or subsequent to the course of MP classes, dependent upon clinical need. The MP intervention consisted of six, 1-h group classes, of six to eight women, run at 1-week intervals by a physiotherapist with specialist qualifications in Pilates. The focus of the MP exercises was on low-intensity abdominal and pelvic floor control, and on the awareness of posture and breathing thought to promote a mind–body connection. The instructor guided the class through a continuous flow of low-level exercises, while keeping patients engaged with their mind–body connection by using descriptive cueing and visualization techniques (for details regarding content of SPC and SPC+MP, see Fig. 2).

Qualitative and quantitative analyses

A lack of existing data about the effectiveness of MP delivered in a group setting meant that precise sample size estimates were not possible. A sample size of 100 was, therefore, determined since it was anticipated that 50 participants per arm would enable detection of a difference of 10 with an SD of 15 on quality of life (QoL) measurements (I-QOL and ICIQ-LUTSqol), and a difference of 2 with a SD of 3 on the SSI, with a power of 70% for a Bonferroni-adjusted

5% significance level (Hollander & Wolfe 1999). Assumptions regarding QoL indices and SSIs were justified by Lamb *et al.* (2009); the RSES (Rosenberg 1965) was assumed to follow a similar pattern. Calculations allowed for 20% attrition, i.e. 40 participants in each group with completed measurements.

Statistical analyses were performed using the R language and environment for statistical computing and graphics (version 3.3.1; RCT 2016). As the data were ordinal and discrete, and did not justify the assumption of normal distribution, the Wilcoxon–Mann–Whitney test was used to: assess the baseline characteristics of the study population (aim 2); test the differences of pre- and post-tests of all outcome measures between the two groups, i.e. SPC+MP and SPC (aim 3); and evaluate the impact of SPC+MP in comparison to SPC in the study population, and in the low and high SSI strata (aim 3). To quantify the size of the difference between the two groups, i.e. SPC+MP and SPC, Cohen’s standardized effect size was calculated in the strata (aim 3). Describing the reliability of the questionnaires was considered an important aspect of exploring the feasibility of the study protocol (aim 1) since, even when outcome measures are standardized and well-published, it cannot be assumed

that they are reliable within a particular target population.

In addition, 16 women (eight from each group) were interviewed at T2, and 15 at T3 (one withdrew). The sample was selected to reflect diversity across a number of variables: age, ethnicity, BMI and SSI (aim 4). All interviews were recorded, transcribed verbatim and analysed using the principles of the framework approach (Ritchie & Spencer 1994; Ritchie *et al.* 2003). A coding frame of key codes and categories was created, and the transcripts coded within MAXQDA (VERBI GmbH, Berlin, Germany), a software package specifically designed to assist with the analysis of qualitative data. The rigour of this process was enhanced by independent review of the transcripts, and categorization of main themes to emerge by the qualitative researcher, principal investigator and research physiotherapist (Lincoln & Guba 1985).

Results

Observations with missing data were included in the analysis based on the following criteria: for average scores, each observation had to have no more than one unanswered item, while simple

sum scores were created using only those observations with complete responses. For all analyses, a two-tailed *P*-value less than 0.05 was considered statistically significant, and a *P*-value between 0.05 and 0.1 was interpreted as indicating a trend.

Baseline characteristics of the study population

There were no significant differences in terms of mean and standard deviation for age, BMI, SSI, self-esteem or QoL, indicating that, at baseline, the SPC and SPC+MP groups were similar, and randomization worked well (see Table 1).

The psychometric properties of the main outcome measures showed excellent internal consistency (Cronbach's $\alpha \geq 0.9$) for the RSES and I-QoL, and good internal consistency ($0.7 \leq \alpha < 0.9$) for the SSI and ICIQ-LUTSqol.

Outcome measures main analysis

From the 36 women allocated to the intervention (SPC+MP) group and the 37 women allocated to the control (SPC) group, 14 and 10 women, respectively, were removed from the complete case analysis for the following reasons: failed to

Table 1. Median (*Md*), interquartile range (IQR), mean (*M*), standard deviation (SD) and *P*-values of all pre-test measurements: (SPC) standard physiotherapy care; (MP) modified Pilates; (BMI) body mass index; (SSI) Symptom Severity Index; (SII) Symptom Impact Index; (RSES) Rosenberg Self-Esteem Scale; (I-QOL) Incontinence Quality of Life Questionnaire; (ALB) Avoidance and Limiting Behaviour; (PS) Psychosocial Impacts; (SE) Social Embarrassment; (ICIQ-UI-SF) International Consultation on Incontinence Questionnaire – Urinary Incontinence – Short Form; and (ICIQ-LUTSqol) International Consultation on Incontinence Questionnaire – Lower Urinary Tract Symptoms Quality of Life*

Variable	Group					Group					<i>P</i> -value
	SPC					SPC+MP					
	<i>n</i>	<i>Md</i>	IQR	<i>M</i>	SD	<i>n</i>	<i>Md</i>	IQR	<i>M</i>	SD	
Age (years)	37	50.00	21.00	48.97	12.25	36	50.50	20.50	51.28	14.15	0.53
BMI	37	28.36	5.64	28.63	4.69	36	28.35	6.50	28.69	4.77	0.80
SSI	37	13.00	7.00	12.53	4.09	36	12.25	8.00	11.45	4.54	0.34
SII	37	6.00	3.00	6.60	3.11	36	5.00	3.00	5.67	2.37	0.24
RSES	37	20.00	10.00	20.58	6.26	36	23.00	5.25	22.44	5.15	0.16
I-QOL:											
ALB ^b	37	56.25	37.50	51.10	23.43	36	46.88	31.25	49.83	22.05	0.72
PS ^b	37	66.67	44.44	57.28	27.83	36	65.28	42.36	62.27	22.99	0.43
SE ^b	37	30.00	45.00	32.84	26.13	36	27.50	41.25	34.17	26.66	0.84
Total ^a	37	52.27	39.77	49.48	23.27	36	49.43	33.81	51.36	21.21	0.71
ICIQ-UI-SF	37	13.00	8.00	12.68	4.66	34	12.50	7.00	12.18	4.75	0.59
ICIQ-LUTSqol:											
Role limitations	37	50.00	50.00	45.05	31.64	36	41.67	33.33	48.61	28.56	0.70
Physical limitations	37	50.00	33.33	50.90	24.20	36	50.00	33.33	51.85	26.06	0.99
Social limitations	37	22.22	55.56	30.93	31.00	36	19.44	47.22	27.16	26.55	0.71
Personal relationships	28	33.33	83.33	38.69	36.87	32	16.67	50.00	30.21	36.28	0.31
Emotions	37	33.33	44.44	44.14	32.23	36	33.33	47.22	36.73	27.71	0.36
Sleep/energy	37	33.33	33.33	42.34	26.23	36	33.33	0.00	37.04	22.22	0.30
Severity measures	37	58.33	33.33	54.73	22.44	36	50.00	37.50	50.69	26.98	0.43
Overall score ^c	37	38.60	34.86	45.66	21.92	36	36.16	26.46	41.17	22.05	0.36

*N.B. All group comparisons were made using the Wilcoxon–Mann–Whitney test. For the I-QOL total (^a), higher scores indicate greater quality of life, whereas, for its subscales (^b), higher scores indicate less ALB, PS and SE. For the ICIQ-LUTSqol overall score (^c), higher scores denote increased impact on quality of life.

Table 2. Median (*Md*), interquartile range (IQR), mean (*M*), standard deviation (SD) and *P*-values of all pre-test measurements with complete follow-up: (SPC) standard physiotherapy care; (MP) modified Pilates; (BMI) body mass index; (SSI) Symptom Severity Index; (SII) Symptom Impact Index; (RSES) Rosenberg Self-Esteem Scale; (I-QOL) Incontinence Quality of Life Questionnaire; (ALB) Avoidance and Limiting Behaviour; (PS) Psychosocial Impacts; (SE) Social Embarrassment; (ICIQ-UI-SF) International Consultation on Incontinence Questionnaire – Urinary Incontinence – Short Form; and (ICIQ-LUTSqol) International Consultation on Incontinence Questionnaire – Lower Urinary Tract Symptoms Quality of Life*

Variable	Group										<i>P</i> -value
	SPC					SPC+MP					
	<i>n</i>	<i>Md</i>	IQR	<i>M</i>	SD	<i>n</i>	<i>Md</i>	IQR	<i>M</i>	SD	
Age (years)	27	51.00	16.00	51.11	10.76	22	52.00	21.50	53.41	12.85	0.55
BMI	27	27.55	6.15	28.60	5.08	22	26.68	7.21	27.89	5.33	0.74
SSI	27	13.00	5.13	13.17	3.65	22	11.50	6.75	10.84	4.70	0.08
SII	27	6.00	3.50	6.74	3.10	22	5.00	2.75	5.55	2.42	0.16
RSES	27	20.00	10.00	20.76	6.50	22	24.00	5.00	23.27	4.34	0.18
I-QOL:											
ALB ^b	27	53.12	34.38	48.61	20.03	22	46.88	28.13	49.72	21.37	0.98
PS ^b	27	66.67	45.83	56.79	26.23	22	69.44	43.75	62.25	23.98	0.37
SE ^b	27	30.00	37.50	31.85	24.97	22	30.00	38.75	34.55	23.09	0.66
Total ^a	27	51.14	39.77	48.15	21.24	22	51.14	32.67	51.39	20.58	0.58
ICIQ-UI-SF	27	13.00	6.50	12.56	4.68	22	12.50	8.00	11.68	5.29	0.51
ICIQ-LUTSqol:											
Role limitations	27	50.00	41.67	44.44	31.35	22	33.33	33.33	49.24	30.64	0.71
Physical limitations	27	50.00	33.33	52.47	22.98	22	41.67	29.17	48.48	27.17	0.40
Social limitations	27	22.22	38.89	27.57	29.62	22	22.22	47.22	28.79	27.30	0.79
Personal relationships	20	33.33	70.83	40.83	36.86	19	16.67	83.33	37.72	41.52	0.62
Emotions	27	33.33	33.33	41.56	29.17	22	27.78	44.44	35.86	28.26	0.48
Sleep/energy	27	33.33	33.33	45.68	24.28	22	33.33	12.50	39.39	24.48	0.28
Severity measures	27	58.33	16.67	56.17	17.69	22	45.83	39.58	50.76	27.81	0.36
Overall score ^c	27	38.60	26.64	45.55	18.63	22	31.58	28.59	41.67	23.64	0.29

*N.B. All group comparisons were made using the Wilcoxon–Mann–Whitney test. For the I-QOL total (^a), higher scores indicate greater quality of life, whereas, for its subscales (^b), higher scores indicate less ALB, PS and SE. For the ICIQ-LUTSqol overall score (^c), higher scores denote increased impact on quality of life.

attend the scheduled treatments (10 SPC+MP; 7 SPC); medical reasons (1 SPC+MP; 1 SPC); and lost to follow-up (3 SPC+MP; 2 SPC). This left a total of 49 participants with a mean age of 52.14 years (SD=11.67 years). The SPC group (*n*=27) had a mean age of 51.11 years (SD=10.76), and the SPC+MP group (*n*=22) a mean age of 53.41 years (SD=12.85). The medians, interquartile range, means, standard deviations and *P*-values of all pre-test measurements with complete follow-up are shown in Table 2. No differences between the two groups, except a trend for the SSI (*P*=0.08), which was lower in the intervention group (SPC+MP) than in the controls (SPC), were observed.

The control group (SPC) had an average of 5.63 SPC sessions [median (*Md*)=6 sessions], whereas the intervention group (SPC+MP) had an average of 4.27 SPC sessions (*Md*=4 sessions). The average length of time between SPC session 1 and session 2 was 12.92 days (*Md*=11 days). The average time between the first and the last SPC session was 167.6 days (*Md*=177 days) for the SPC group, and 135 days (*Md*=152 days) for the SPC+MP group.

The pre- and post-test measurements of the main outcome variables (primary analyses)

showed no significant differences between the two groups (Table 3).

Outcome measures main analysis in strata

Post-intervention participants in the SPC+MP group with low SSI scores showed significant increases in self-esteem [standardized effect size (*d*)=0.79, *P*=0.032], felt less social embarrassment (*d*=0.73, *P*=0.026) and were less affected by UI in their normal daily activities (*d* = -0.73, *P*=0.025) when compared to the SPC group. Furthermore, positive trends in the SPC+MP group indicated that, post-intervention, women with low SSI scores had a higher overall QoL score (*d*=0.65, *P*=0.052), and their social life was less impacted by the UI symptoms (*d* = -0.60, *P*=0.089) in comparison to the women in the SPC group. In contrast, SPC+MP group participants with high SSI scores showed significant improvements in their personal relationships (*d* = -1.10, *P*=0.017) between pre- and post-test assessments when compared with those receiving SPC only. The box plots for the differences between pre- and post-test assessments of self-esteem and QoL dimensions illustrate the combined effect of SPC and MP between T1 and T3 (see Fig. 3).

Table 3. Median (*Md*), interquartile range (IQR), mean (*M*), standard deviation (SD) and *P*-values of all pre- and post-test differences: (SPC) standard physiotherapy care; (MP) modified Pilates; (BMI) body mass index; (SSI) Symptom Severity Index; (SII) Symptom Impact Index; (RSES) Rosenberg Self-Esteem Scale; (I-QOL) Incontinence Quality of Life Questionnaire; (ALB) Avoidance and Limiting Behaviour; (PS) Psychosocial Impacts; (SE) Social Embarrassment; (ICIQ-UI-SF) International Consultation on Incontinence Questionnaire – Urinary Incontinence – Short Form; and (ICIQ-LUTSqol) International Consultation on Incontinence Questionnaire – Lower Urinary Tract Symptoms Quality of Life*

Variable	Group										<i>P</i> -value
	SPC					SPC + MP					
	<i>n</i>	<i>Md</i>	IQR	<i>M</i>	SD	<i>n</i>	<i>Md</i>	IQR	<i>M</i>	SD	
SSI	27	−3.00	4.50	−2.32	3.76	22	−1.50	3.38	−1.99	3.00	0.58
SII	27	−2.00	3.50	−1.82	2.06	22	0.00	3.00	−0.82	1.94	0.08
RSE	27	0.00	4.50	−0.20	2.99	22	1.00	4.50	0.86	3.32	0.21
I-QOL:											
ALB ^b	27	9.38	20.31	14.70	17.97	21	12.50	21.88	16.82	20.76	0.47
PS ^b	27	8.33	16.67	8.58	16.40	22	13.88	19.53	15.55	22.69	0.15
SE ^b	27	15.00	25.00	15.00	19.36	22	22.50	27.50	23.86	24.39	0.10
Total ^a	27	12.50	21.59	12.23	15.89	21	15.91	18.24	17.96	21.10	0.18
ICIQ-UI-SF	22	−3.00	3.75	−3.27	2.57	17	−3.00	5.00	−3.06	4.13	0.51
ICIQ-LUTSqol:											
Role limitations	27	−16.67	25.00	−15.43	23.99	22	−16.67	16.67	−21.97	22.65	0.098
Physical limitations	27	0.00	33.33	−12.96	25.04	22	−16.67	33.33	−14.39	29.23	0.83
Social limitations	27	0.00	16.67	−9.47	28.86	22	−13.89	33.33	−18.69	25.11	0.13
Personal relationships	19	0.00	8.33	−8.77	26.86	19	−16.67	25.00	−14.91	39.24	0.16
Emotions	27	−11.11	22.22	−8.64	23.33	22	−11.11	27.78	−10.61	24.36	0.91
Sleep/energy	27	−16.67	33.33	−9.88	23.23	22	−8.33	16.67	−6.06	19.62	0.74
Severity measures	27	−8.33	16.67	−6.48	16.23	22	−8.33	16.67	−10.61	16.50	0.28
Overall score ^c	27	−9.26	11.35	−10.76	16.85	22	−10.87	17.25	−13.38	17.80	0.44

*N.B. All group comparisons were made using the Wilcoxon–Mann–Whitney test. For the I-QOL total (^a), higher scores indicate greater quality of life, whereas, for its subscales (^b), higher scores indicate less ALB, PS and SE. For the ICIQ-LUTSqol overall score (^c), higher scores denote increased impact on quality of life.

Qualitative findings

From the information provided by women attending SPC only, it appeared that these sessions were individually tailored, but always included detailed PFMT. While benefits were reported in terms of some improvement in physical symptoms, by T3, a plateau appeared to have been reached, and even those most committed to continuing PFMT described feeling “demoralized” or doubting the effectiveness of this approach to treatment in the long term.

Allocation to the SPC+MP group was generally met with enthusiasm, and women in this group seemed aware of the general health benefits of Pilates. Overall, experiences of the classes were positive and related to: the gentle approach to exercise; undertaking exercises in different positions; frequency and intensity of undertaking the exercises; and a sense of fun and enjoyment. A number of aspects appeared to impact positively on the women’s emotional experience, in particular the group support encountered, and a sense of “feeling safe” both physically and emotionally. Improvements in symptoms reported by the SPC+MP group resulted both from a perceived increase in the strength of their PFMs, and a greater awareness of how and when to use PFMs to avoid leakage in everyday situations.

Some concern and disappointment was also expressed that improvements were not as great as had been hoped, or required conscious management, and an association emerged from the data between SSI scores and the perceived effectiveness of MP classes. In addition to changes in UI symptoms, some women, in particular those with higher self-esteem, spoke about the value of the MP classes in terms of what it taught them about themselves and their bodies; for example, motivating them to continue looking after themselves through increased exercise and attention to diet. Others also described increased confidence in undertaking activities, such as going out for a walk. In terms of the acceptability of MP classes, a number of suggestions were made. These included: the importance of using everyday language rather than medical terms; a preference to know whether all group members suffered from UI; the importance of continuity between SPC and treatment provided in the MP classes; the potential value of “take home” instructions; and some practical issues, such as the timing of groups and facilities available.

Discussion

The quantitative results of this pilot trial confirmed that the baseline characteristics of the

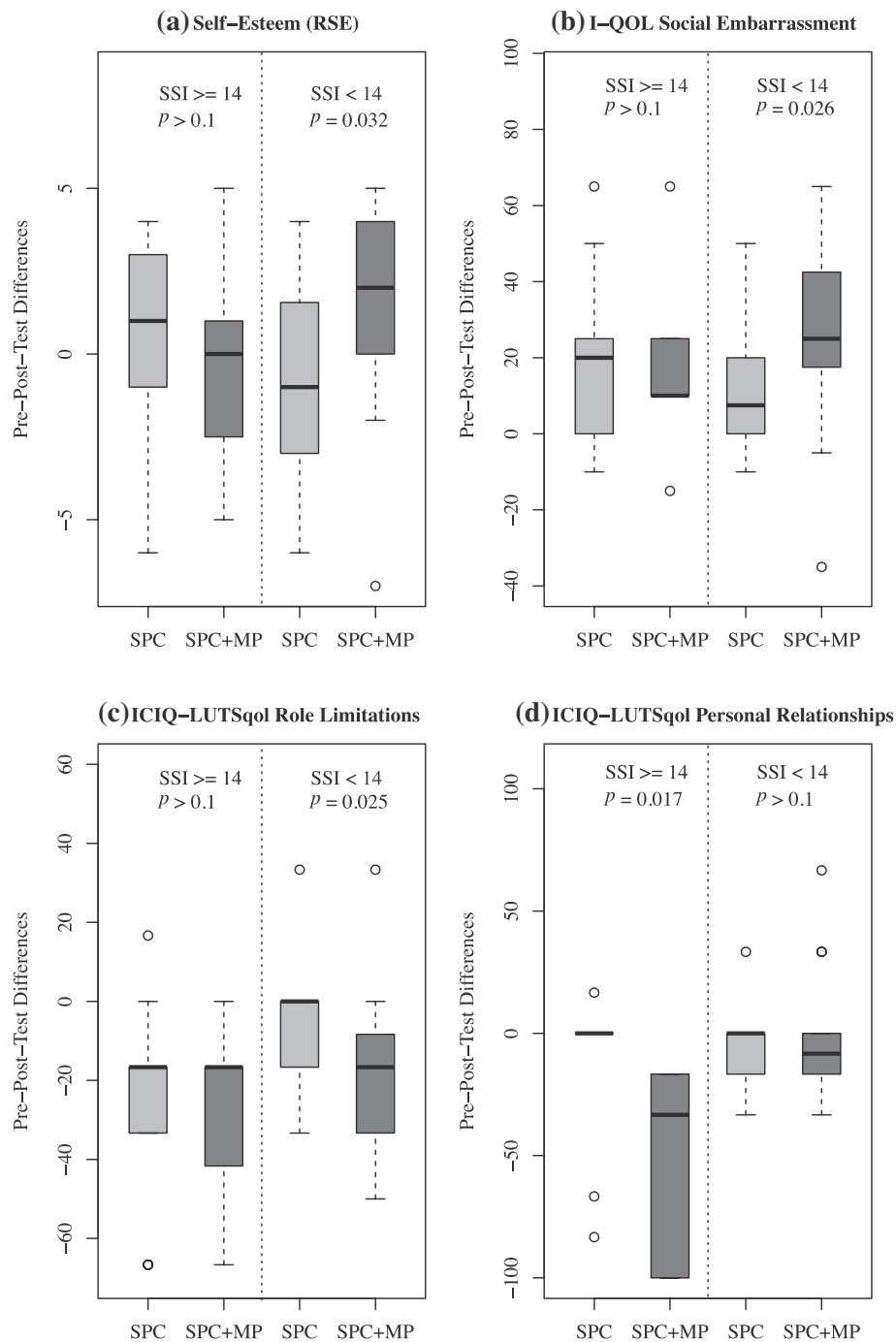


Figure 3. Box plots of pre- and post-test differences in (a) self-esteem, (b) social embarrassment, (c) normal daily activities and (d) social life for participants with low and high Symptom Severity Index (SSI) scores. N.B. On the y-axis, positive values of pre- and post-test differences indicate improved self-esteem [Rosenberg Self-Esteem Scale (RSE)] and reduced embarrassment [Incontinence Quality of Life Questionnaire (I-QOL) – Social Embarrassment (SE)], whereas negative values indicate that the women were less affected by incontinence in their normal activities (e.g. job) [International Consultation on Incontinence Questionnaire – Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol) – Role Limitations Personal Relationships]. Key: (SPC) standard physiotherapy care; and (MP) modified Pilates.

two groups were similar (i.e. that the randomization worked), and the outcome measures had high reliability (Cronbach’s $\alpha > 0.80$). The data revealed a range of benefits for women who attended MP classes in addition to SPC (i.e. improved self-esteem, decreased social embarrassment, less impact on normal daily activities and

improved personal relationships), especially for women with lower symptom severity. In addition, the qualitative analysis supported these findings, and also indicated that MP classes could positively influence attitudes to exercise, diet and well-being. It is possible that some of the outcomes observed could be the results of

the benefits of attending a class or group other than the MP exercises. However, the purpose of this pilot study was to evaluate the effectiveness of MP classes as a whole experience, rather than attempt to isolate the effects of MP exercises, since it is the delivery of MP in a group or class setting that is most likely to prove cost-effective for the NHS.

Comparison with existing literature

Similar to previous studies (Savage 2005; Culligan *et al.* 2010), the present sample was not sufficiently powered to make clear inferences about the effectiveness of the intervention, and therefore, until further results are produced, this approach should not be recommended for routine use in clinical practice. Unlike previous research, our pilot trial aimed to assess the feasibility of the study protocol (testing phase) in order to conduct a future high-quality RCT. Although the impact of including MP as an adjunct to SPC has not yet quite been established, the results of this study identify patterns that warrant further investigation. Therefore, with a number of modifications, it appears feasible to transfer the research protocol of this pilot study to a larger multicentre trial.

Strengths and limitations

This is the first clinical trial to assess the efficacy of MP classes in the management of UI using a mixed-methods approach. The study provides new insights into the possible positive effects of the intervention, and its implementation in practice. However, the study sample was not sufficiently powered to establish conclusively whether the addition of MP classes as an adjunct to SPC for women with UI is of benefit (i.e. this might have been only the result of chance accounted for in the statistical analysis). Moreover, the duration of the intervention was short relative to the duration of UI, making it difficult to reliably capture the efficacy of MP classes, and although the supervised SPC sessions were provided in accordance with NICE guidelines (NICE 2006, 2013), this was less frequent than in the research from which these guidelines were developed. Despite several modifications made to improve recruitment to the study (based on the feedback from potential participants and the project PPI group), another challenge posed by this trial was the retention rate at follow-up. Consequently, a complete dataset was obtained for about two-thirds of the randomized patients.

The observation that 14 women in the SPC+MP group compared to 10 in the SPC-only group withdrew from the study could challenge the assumption that MP classes have the potential to improve motivation and commitment to exercise believed to be beneficial for UI. Findings from the interviews and discussion with the project PPI group suggest, however, that attrition from the SPC+MP group was most likely to be a result of aspects of delivery; for example, the timing of the classes and geographical location, rather than the nature of the exercises. Moreover, withdrawal from the study does not necessarily equate with cessation of exercise. It is, therefore, essential that aspects of delivery and subsequent adherence to exercise are fully explored in a definitive trial so that potential delivery in the NHS is fully informed.

This study utilized self-reported measures of symptom severity in preference to clinical measures such as pad tests or PFM strength. While this could be viewed as a limitation, members of project PPI group were adamant that inclusion of such invasive measures could seriously impact on recruitment from this particular population of women attending the Women's Health Physiotherapy Service for UI. In addition, it should be noted that the NICE guidelines (NICE 2013) do not recommend the use of pad tests in routine clinical assessment. Most importantly, however, members of the group emphasized that it was the psychological and social impact of UI on their lives, and the potential benefits of treatments in this respect, that required evaluating, rather than the level of incontinence *per se*. This study, therefore, makes an essential contribution to understanding the potential positive benefits of MP for the lives of women who experience UI. It is, however, recognized that exclusion of a clinical measure of leakage limits the impact of this research. Moving forward, intensive work with the PPI group will explore further the risk to recruitment of including such measures (given that recruitment proved to be problematic even without clinical measures), together with the relative importance to women experiencing UI of the degree of incontinence versus their overall sense of well-being. This work will inform the design of future research.

A further aspect to be considered in future designs is the inequality of the two interventions in terms of contact time. To fully understand the potential benefit of MP classes as a treatment for UI in terms of cost to the NHS, the amount and

type of contact received by participants in the two groups will need to be equivalent.

Future research

Given the significant results and positive trends indicated by this study, one important issue for future research is to assess the long-term effects of including MP classes within the management of UI. A future full RCT is, therefore, required, incorporating both a larger sample size and a more-robust follow-up strategy (e.g. administering questionnaires face-to-face). Findings stemming from this pilot indicate that women with low SSI scores were most likely to experience benefits from adjunct MP sessions; however, the study does not provide the complete picture of what can be expected in clinical practice. Thus, future research could explore whether focusing only on women with a lower SSI score makes greatest clinical and socioeconomic sense. Additional contributions could be made by comparing the effects of MP classes with other forms of therapy (e.g. cognitive-behavioural therapy) or other forms of group support, and also through considering the potential impact of MP classes on the number of SPC sessions that are required.

Implications for practice

The use of both qualitative and quantitative methods to evaluate the effectiveness of MP delivered in a group setting, which, until now, has been based purely on anecdote, provides a greater understanding about such an approach, and ensures that the voice of patients contributes to the development of practice. Given the negative impact of UI on social health and well-being, this type of exploration is greatly needed to understand fully the longitudinal impact of UI, and reduce the psychological burden on patients and their family. Also, such an approach could provide an important alternative treatment for women wishing to avoid surgery, be cost-effective, reduce impact on job participation and provide long-lasting health benefits. Finally, it might serve as a point of departure for clinicians designing intervention strategies, which could help individuals affected by this condition develop the necessary skills and empowerment to help manage the challenges associated with incontinence.

Conclusion

In summary, the global scores of the pre- and post-test differences were comparable between

the groups (i.e. SPC and SPC+MP). Secondary subgroups analyses indicated that SPC+MP in comparison to SPC improved self-esteem, normal daily activities and reduced the feelings of embarrassment in women with low SSI scores, and for women with high SSI scores, improved their personal relationships.

Taken altogether, the results of the pilot trial provide important parameter estimates to plan the recruitment, the sample size and the number of trial centres of the full trial. Moreover, the evaluation of the instruments allows the selection of an efficient set of questionnaires to assess the effectiveness of including MP as an adjunct to standard physiotherapy care for women with urinary incontinence.

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Availability of data and materials

The quantitative dataset generated and analysed for the current study is available from the corresponding author on reasonable request. The qualitative data set is not publicly available since consent was not obtained from participants

for the sharing of their interview material. These data may be made available upon reasonable request if consent from participants can be subsequently obtained.

Additional file

Outcome measures – a description of the four outcome measures/questionnaires used: Symptom Severity Index (SSI)/Symptom Impact Index (SII); Incontinence Quality of Life Questionnaire (I-QOL); International Consultation on Incontinence Questionnaire (ICIQ); Rosenberg Self-Esteem Scale (RSES): https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5767028/bin/12905_2017_503_MOESM1_ESM.docx

Authors' contributions

A.L. and L.M. prepared the drafts of this paper, which were revised by S.H., J.J. and B.L. for accuracy and intellectual content. A.L. was responsible for the collection and management of quantitative data throughout the project, and undertook quantitative analysis overseen by B.L. L.M. was responsible for the qualitative interviewing and analysis. S.H. was the project chief investigator, and therefore, key to the conception and ultimate delivery of the research. J.J. was the senior academic physiotherapist on the project, and provided essential clinical and methodological insights in addition to project management support. B.L. was responsible for the statistical elements of the study design. All authors have given approval for the current version to be submitted, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Notes

Ethics approval and consent to participate

The study was approved by the NRES East of England Hertfordshire Ethics Committee Reference 12/EE/0241 on 18 July 2012, with a substantial amendment approved 24 June 2013. Written consent, including the voluntary nature of participation and the right to withdraw without medical care being affected, was obtained from each participant by the research physiotherapist.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Footnotes

Electronic supplementary material

The online version of this article (DOI: 10.1186/s12905-017-0503-y) contains supplementary material, which is available to authorized users.

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Adi Lausen studied psychology and philosophy at Friedrich-Alexander University Erlangen-Nürnberg, Germany, and the University of Essex. He currently works in the Department of Affective Neuroscience and Psychophysiology at the University of Göttingen, where he is writing up his PhD thesis.

Having qualified as a registered mental health nurse and a complementary therapist, Louise Marsland is an experienced health researcher with a long-standing interest in health issues. She has coordinated large-scale studies funded by the Department of Health, Home Office and Economic and Social Research Council, and currently works as a research adviser for the NIHR Research Design Service. Louise has an eclectic mix of research interests, including complementary therapies, cancer care, brain injury, women's health and vulnerable young people.

Samantha Head is a senior chartered physiotherapist with 15 years of experience in the NHS, who now works predominantly in the field of women's and men's health physiotherapy. She also has a specialist interest in fitness and health, has an MSc in Sports Science (Fitness and Health), and is a qualified Pilates instructor. Alongside her NHS work, Samantha also

practises within a private physiotherapy clinic, treating women's and men's health patients, and teaches a range of Pilates and fitness classes in the community. She has a keen interest in research and treatment development within her specialist women's health field, and was involved in designing and initiating the women's health research project.

Jo Jackson is the Director of Research and Professor of Physiotherapy in the School of Sport, Rehabilitation and Exercise Sciences at the University of Essex. She was previously the Dean of Health at the university, with responsibility for contracting and commissioning activities with Health Education England in the Midlands and East. Jo represents the university on the Local Workforce Advisory Board for Northern East Essex and Suffolk, and is a governor at CHUFT. She is currently undertaking research in the areas of women's health, and gait and falling in older people.

As Head of Department and Professor of Data Science, Dr Berthold Lausen is affiliated with the Department of Mathematical Sciences at the University of Essex. He is a member of the Institute for Analytics and Data Science, the Essex Biomedical Sciences Institute, and as Professor in Biometrics and Epidemiology, an external member of the Medical School of Friedrich-Alexander University Erlangen-Nürnberg. Berthold studied statistics at the Faculty of Statistics, Technical University

of Dortmund, Dortmund, Germany. Berthold serves as president-elect (2018–2019) of the International Federation of Classification Societies, president of the Gesellschaft für Klassifikation Data Science Society and president of the European Association for Data Science.

Following the present successful feasibility and pilot study, the authors are now preparing a funding application for a full multicentre trial. They will be making small adjustments to the original protocol, but are seeking expressions of interest from women's health services that might be interested in being involved as a site for the main study. A site will need to be able to offer Pilates classes, for which full training will be provided, alongside their standard physiotherapy service. If you would like to find out more, please contact Jo Jackson (e-mail: jo.jackson@essex.ac.uk).

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