Exercise intervention in the management of urinary incontinence in older women in villages in Bangladesh: a cluster randomised trial

Adrian Wagg, Zafurrullah Chowdhury, Jean-Michel Galarneau, Rezaul Haque, Fardous Kabir, Dianna MacDonald, Kamrun Naher, Yutaka Yasui, Nicola Cherry

Summary

Background Group exercise-based programmes for urinary incontinence appear to be promising low-cost interventions for women in developing countries, but no evidence exists to support whether they could be implemented or effective in such populations. We aimed to evaluate whether a group intervention that comprised pelvic floor muscle training, mobility exercises, and bladder education would be more effective than education alone, and report changes between villages (ie, clusters) rather than between individual participants.

Methods In this cluster randomised trial, we recruited women from 16 pairs of villages in Bangladesh, with each pair comprising similar villages from the same sub-district. Women aged 60–75 years were interviewed to establish eligibility. Women were eligible if they had current urinary incontinence, and were excluded if they had a third degree or higher uterine prolapse, if they were unable to walk or stand without help, or if they had insufficient intellectual capacity to understand questions and follow instructions. The villages were randomly assigned within each pair to either exercise plus education or education-only intervention by use of a random number generator from a fixed seed. Women were excluded after consenting if they lived too far from the centre of the village. The exercise intervention was a physiotherapist-led group exercise class that was held twice weekly for 12 weeks, with home exercises between classes and to 24 weeks. Both groups received bladder-health education. Participants were followed up for 24 weeks. A 3-day continence record was collected at recruitment and every 4 weeks up until 24 weeks. This record involved the participant tying a knot in ribbons worn under the clothing each time they had an episode of urinary leakage. The primary outcome was change in number of knots (recorded leakage episodes) from recruitment to 24 weeks. Safety was assessed in all participants in the exercise intervention group. The trial is registered at ClinicalTrials.gov, number NCT02453100.

Findings Between Aug 22, 2015, and July 2, 2018, of 3577 women aged 60–75 years identified, 1003 were eligible, of whom 625 consented to participate (n=335 exercise plus education villages, and n=290 in education-only villages). Of these consenting women, 46 were excluded (n=37 exercise plus education, n=9 education only) because they lived too far from the centre of the village. At week 24, 283 (95%) of 298 in the exercise plus education group and 274 (98%) of 281 in the education-only group completed a 3-day continence record. The estimate of change in number of leakage episodes between baseline and 24 weeks was –7·7 (95% CI –10·6 to –4·8) at the village level in an unadjusted model, and –6·64 (–7·95 to –5·33) in a random-effects model accounting for cluster randomisation. No adverse events were reported.

Interpretation A structured group-exercise intervention has the potential to manage urinary incontinence in older women in communities largely outside the reach of pharmaceutical or surgical interventions.

Funding Canadian Institutes for Health Research.

Introduction Urinary incontinence is a common condition with a profound effect on wellbeing and quality of life.1 Good evidence exists that urinary incontinence can be managed by use of exercise-based interventions2 but little is known about whether these interventions would be feasible or effective in developing countries. A study carried out among more than 43,000 villagers aged 60 years or older, under the care of Gonoshasthaya Kendra (a non-governmental organisation registered in 1972 to serve rural villages in Bangladesh and responsible for health in 615 villages), found 30% of older women reported urinary incontinence, which was strongly associated with depression.3 In May to June, 2011, discussions in Bangladesh with Gonoshasthaya Kendra health workers and village women suggested that an exercise intervention to help manage incontinence, using the existing structures and personnel within Gonoshasthaya Kendra, would be welcome and feasible. A Cochrane review4 has concluded that pelvic floor muscle training (PFMT) is effective for women with stress, urgency, or mixed urinary incontinence. The
recommended first-line conservative therapy is PFMT of at least 3 months duration, which ideally should be supervised.¹ The efficacy of this therapy is well established and is the basis of inclusion in national and international treatment guidelines.²-⁴ No trial of PFMT has been reported in Bangladesh to date, but the effectiveness of this training has been shown in a randomised controlled trial from India (in women aged 18–80 years).⁷ Interventions that address mobility have also been found to be effective in treating undifferentiated incontinence.⁸-¹¹ An approach using a combination therapy of both mobility exercise and PFMT resulted in a decrease in urinary incontinence using a twice weekly 1 h intervention over 3 months in Japanese women aged 70 years or older,¹²,¹³ and formed a starting point for the design of the intervention reported here.

To provide strong evidence on the effectiveness of such an exercise-based approach in rural Bangladesh, we designed a cluster randomised trial in collaboration with Gonoshasthaya Kendra. Within Gonoshasthaya Kendra, costs of care are graduated by income, with the very poor and destitute receiving care at minimal or no cost. Village health care is coordinated through health centres covering several villages. Each village is assigned a paramedic who carries out prenatal care, birth assistance, and other gynaecological procedures, and provides front-line care for all family members, including the older generations. The structure of the Gonoshasthaya Kendra organisation, with central planning and training but with little communication between residents of different villages, provided a favourable setting for a cluster randomised trial. In this study, we aimed to evaluate a group intervention, randomised by village, and relate changes between village clusters rather than between individual participants. The primary endpoint was to determine whether an intervention that comprised PFMT and mobility exercises plus bladder education would be more effective than bladder education alone in decreasing urinary incontinence in older women in the villages who have little recourse to other treatment.

**Methods**

**Study design and participants**

In this cluster randomised trial, we recruited 32 villages that are served by Gonoshasthaya Kendra from six districts of Bangladesh: Gazipur, Pabna, Chapai, Bhola, Sherpur, and Gaibandha. Villages were randomly assigned to either an exercise plus education or education-only intervention, with the same intervention being given to every eligible and consenting woman in a village. To help minimise unmeasured confounding, randomisation was carried out within pairs from the same subdistrict (upazila). At the time of planning the study, Gonoshasthaya Kendra had 45 health centres sited in 20 of Bangladesh’s 64 districts. Only a subset had records of sufficient quality to identify the size, sex–age structure, and socioeconomic status of the villages under its care; other villages were new to the Gonoshasthaya Kendra system, managed in part by some other organisation or serviced only special subgroups (eg, refugees or transient workers). 12 health centres that covered 52 villages had good records were chosen for possible inclusion in the study. We examined the available data for these villages for the following three factors: the number of women aged 60–75 years, distribution of socioeconomic groups (routinely estimated for each family in each village served by Gonoshasthaya Kendra to determine contribution, if any, to health costs), and distance to each village within the same upazila (subdistrict). From the 52 villages, the principal investigator (NC) selected the 16 study pairs first by eliminating villages with few women in the target age range. Second, to decrease the risk of contamination, pairs were chosen with the greatest...
distance between them, within a subdistrict. Finally, pairs were matched up with similar proportions of poor or very poor inhabitants.

Each village had been assigned a paramedic by Gonoshasthaya Kendra, and over 40 of these paramedics took part in this project, all of whom were women.

All women thought to be aged 60–75 years were identified by use of the family card that is routinely updated by the village paramedic when any event occurs in that household (births, deaths, change in household composition). A home visit was made by the village paramedic to complete a brief screening questionnaire in Bangla to determine eligibility. Women were eligible if they were aged 60–75 years, as recorded on the family card and confirmed by the woman, and had current urinary incontinence, with a positive response to one or more of questions 2, 3, or 4 (on urinary leakage with urgency, stress, or drops of urine loss) from the six-item Urinary Distress Inventory (UDI) Short Form (version 6).16 Women were excluded if they had a uterine prolapse of third degree or higher, determined by asking each woman if she had any uterine prolapse. The paramedic then recorded whether she believed it to have been third degree or higher (ie, the cervix protrudes outside the vagina). Since village paramedics provided health care to these women, they would be likely to know of such an issue, and were not asked to carry out a physical examination before recording the presence of this condition. Furthermore, the paramedic assessed whether the women were able to sit from sitting without help, walk without help at a normal pace for someone of their age, and had the intellectual capacity to understand the paramedic’s questions and follow instructions; women were excluded if they did not meet one or more of these criteria.

In every selected village, a village meeting was called to explain in broad terms that a study was being carried out to promote healthy lifestyles in older women, but without focusing on urinary incontinence, to allay curiosity about the presence of the research team in the village. All eligible women in a village were invited to take part in the trial. Women were asked for consent at the first home visit. However, women who consented but whose homes were determined to be too distant from the centre of the village for their inclusion to be practical were excluded on distance.

Consent was signified by a witnessed thumbprint after a verbal explanation of the purpose of the trial and of the processes that would be involved for those taking part. The protocol was approved by the National Research Ethics Committee of the Bangladesh Medical Research Council (BMRC/NREC/2013-2016/933) and the Heath Ethics Research Committee of the University of Alberta, AB, Canada (Pro00050317). The protocol is available online. As outlined in our study proposal, a data monitoring committee was formed, with two North American and two Bangladeshi members. No issues arose that required a formal meeting and so none was held. Medical Research Council guidance on cluster recruitment16 was followed.

Randomisation and masking
After choosing the 16 pairs of villages, one village in each pair was randomly assigned to the exercise plus education group and the other to the education-only group by use of a random number generator from a fixed seed. Allocations within each pair, generated by the study biostatistician (YY), were transferred to 16 sealed, opaque, numbered envelopes by a third party and the other investigators and the field workers were masked to allocation.

The nature of the intervention was disclosed by the principal investigator (NC) to investigators in Bangladesh after determination of eligibility of women in that pair of villages but before consent was obtained from the women (protocol deviation). Women in the villages were told only about the intervention to which they had been allocated. Once the allocation was revealed, everyone was unmasked (ie, participants, research staff, and coding staff).

Procedures
In April, 2012, before the full trial was launched, a pre-test was done in two Gonoshasthaya Kendra villages (not included in main study) to develop a culturally appropriate exercise plan and to test a 3-day continence record that was developed for use in this largely illiterate population, the results of which have been published previously.18 The 3-day continence record was a belt worn under clothing with ribbons to be knotted by the participant after each episode of urinary leakage. After this pre-test, in 2012–13, a more formal feasibility trial in five villages (not included in main study) was undertaken that provided trial-specific research experience for the Bangladeshi co-investigators, to give the physiotherapists field experience with the group exercise intervention, and to provide data from which to estimate sample size (details are in the protocol).

For this study, senior paramedics from Gonoshasthaya Kendra were designated research paramedics and trained to carry out the research procedures, moving between pairs of villages and covering both villages in each pair. Community physiotherapists—mainly graduates of the Gonoshasthaya Kendra associated university (Gono Bishwabidyalay, Savar upazila, Dhaka District, Division of Dhaka, Bangladesh)—have recently supplemented the work of the Gonoshasthaya Kendra health centres and lead the exercise intervention. Training camps were held with the community physiotherapists, research paramedics (all of whom were women), and field monitors (who checked and coded the data) at the Gonoshasthaya Kendra training centre in Savar, Dhaka District, for 3 days in December, 2014, and 3 days in February, 2016. Physiotherapists were trained to run the exercise class and research paramedics to run the education intervention, how to complete questionnaires, and how to use the ribbon belt to record urinary leakage.
In each village allocated to the exercise plus education group, with the help of senior women in the village, the physiotherapist identified a location that was accessible on foot in which exercise classes could be held with privacy. A meeting was held with all eligible women in these villages and training was given on the 3-day continence record belt by the research paramedic who also ran a group education session on how the urinary system works and how to maintain good bladder habits (for more details see appendix). The physiotherapist explained PFMT and described arrangements for the exercise classes (ie, location, scheduling, privacy, content). The research paramedic then visited each woman at home to ask for consent and to collect baseline data. 3 days later, both the research paramedic and physiotherapist visited the home. The research paramedic reinforced the education message and the physiotherapist then gave individual training to the woman on pelvic floor exercises. Once all women in the village had been through this baseline procedure, group exercises began and continued twice weekly for 12 weeks. The physiotherapist kept a record of attendance at each of the 24 classes.

The exercise intervention entailed 60 min of group exercises done twice weekly for 12 weeks, followed by 30 min of brisk walking. The exercises included both PFMT and mobility exercises (for more details see appendix). The starting level for the exercises was standardised on the basis of the feasibility study with women from other villages. The exercise group was led by one of three community physiotherapists. Fidelity to the protocol was enhanced by the mid-trial training camp (led by DM) and supervision of physiotherapists new to the trial by the senior physiotherapist (KN), who had been closely involved in development of the exercise intervention.

After four exercise classes, the physiotherapist visited each woman at home to identify any problems in carrying out home exercises (designed to be carried out between classes) and to reinforce the PFMT. If either the physiotherapist or the participant had any uncertainty about whether the participant was carrying out these exercises correctly, then, following a procedure found to be acceptable for 42% of women (39 of 93) in the feasibility study (appendix), they would offer to put one finger in the vagina while the woman contracted her pelvic floor muscles and provided further coaching as necessary. A separate consent form was required and a thumbprint obtained if the woman opted for this extra procedure.

At the end of 12 weeks, the physiotherapist moved to a new village but the research paramedic remained to encourage home exercise, reinforce the education message, and collect data at home visits. In a deviation from protocol, in each village assigned to exercise plus education, the research paramedic organised group exercises in weeks 13–24 and women were offered the option of these extra classes.

For the villages assigned to the education-only group, the intervention was identical to that of the exercise plus education group, including the initial meeting with explanation of the 3-day continence record, except without the physiotherapist-led training in, and practice of, PFMT and mobility exercises and without the home visit from the physiotherapist.

Data were collected from both intervention groups by the research paramedic during a home visit at baseline and at 24 weeks. A urine sample was collected during the baseline visit and tested microscopically on site for the presence of white cells that would suggest an infection. Following Gonoshasthaya Kendra practice, amoxicillin (500 mg every 12 h for 7 days) was given to each woman with over five white cells per high-power field. Baseline information included demographic data and measured height and weight. Weight was also measured at 24 weeks. Data were also collected by use of the five-dimensional EuroQol Questionnaire (EQ5D)\textsuperscript{19} at baseline and 24 weeks for a visual analogue score of health state and subscales to determine participant health-related quality of life and by use of the ten-item Centre for Epidemiologic Studies Depression Scale (CES-D-10) questionnaire\textsuperscript{20} at baseline and 12 and 24 weeks to determine depression state. In addition to data collection at baseline and 24 weeks, every fourth week from week 4 to week 20 the research paramedic visited each woman’s home and attached a 3-day continence record belt, removing it after 3 days. At that point, the paramedic also reinforced the education message, using designated flash cards on drinking more fluids and eating more fruit and vegetables. At week 12, the paramedic repeated the healthy bladder education.

**Outcomes**

The primary outcome was change in number of urinary leakage episodes between baseline and 24 weeks, measured by use of the number of knots made over 3 days in ribbons on the 3-day continence record belt.

Secondary outcomes reported here were change in the EQSD\textsuperscript{19} visual analogue score of health state between baseline and 24 weeks; change in each of the five subscales of the EQSD between baseline and 24 weeks, with the subscales recoded to no problem or some problem; and change in depression score on the CES-D-10\textsuperscript{20} between baseline and 24 weeks. Previously developed and validated Bangla versions were used for the EQSD and CES-D-10 questionnaires.

Other secondary outcomes were questionnaire data reporting severity and distress caused by urinary symptoms with a depression score at 3 months, and will be reported elsewhere.

Proportion of participants cured (ie, no urinary leakage over 3 days on the 24 week 3-day continence record) was not specified in the protocol but was included as an exploratory additional outcome to reflect the importance of this measure for use in future meta-analyses.\textsuperscript{2}
In the exercise plus education villages, adverse events were recorded by the physiotherapist during weeks 1–12 and the research paramedic in weeks 13–24. We had no specific checklist or criteria for adverse events. Reasons for not continuing the trial were recorded by the research paramedic in both exercise plus education and education-only villages.

Statistical analysis
The power of the study was calculated, accounting for the cluster randomisation design,²¹ for the primary outcome, using data from the feasibility study (appendix). The adequacy of the available clusters (set at 16 pairs) was assessed assuming 24 women consented to participate in each village. Thus, the calculation was of the power of the study for a fixed sample size. Although matching of the villages was included in the study design, matches were broken in calculating the power for the assumed analysis, following the work of Diehr and colleagues.²² Although the intraclass correlation (ICC) in the five villages from the feasibility study was close to zero, an ICC of 0·15 was conservatively assumed for power consideration. In the feasibility study, which included only one education and four exercise plus education villages, the mean change in scores from the 3-day continence record in the education village in women who were incontinent at baseline was a decrease of 3·2 knots (SD 4·5). With 16 pairs and an ICC of 0·15, the study had 81% power to detect a 2-point mean difference in leakage between exercise plus education and education-only villages.

We calculated proportions or mean (SD) to summarise demographic information on the participants who were enrolled.

We assessed changes from baseline to 24 weeks in number of leakage episodes and secondary outcomes measured on a continuous scale (health-state scale and depression score), initially unadjusted, by a village-level 𝑡 test (unpaired, per protocol) by a difference-of-differences analysis. We assessed changes at the village level in the five subscales of the EQ5D and proportion of participants cured at 24 weeks using the bootstrap method to estimate CIs. We replaced missing outcome data with the most recent available data for the difference-of-differences analysis. We then did a multilevel model-based evaluation, adjusting for village-level and participant-level random effects using a linear mixed model. The multilevel model-based evaluation, described as the constrained baseline approach by Hooper and colleagues,²³ considered two levels of random effects: at the village level, correlated random effects for the intercept and for the 24-week follow-up time, representing the village-specific departures from the respective overall means, using an unstructured covariance for the bivariate random-effects terms; and at the participant level, with a random intercept representing the participant-specific departure from her village-specific mean (averaged across baseline and week 24), with fixed effects for the intervention at follow-up and the timepoint (baseline or 24 weeks). Kenward-Roger correction was applied for improved accuracy in the large sample inference with the linear mixed model (code is in the appendix). An equivalent model was fitted for the binary outcomes (EQ5D subscales) using multilevel logistic regression. Finally, in a post-hoc

![Flow diagram](image-url)
analysis, both approaches were used to assess the effect of the intervention in women who had elected not to join the additional exercise classes organised by the research paramedic in weeks 13–24—ie, those who adhered to the initial protocol. We used Stata version 15.1 for statistical analyses. The trial is registered at ClinicalTrials.gov, registration number NCT02453100.

Role of the funding source
The funder of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results
Between Aug 22, 2015, and July 2, 2018, of 3577 potentially eligible women identified in the 32 selected villages, 1003 were eligible for inclusion (n=556 in 16 villages in the exercise plus education group, and n=447 in 16 villages in the education-only group) and 625 consented to participate and were enrolled (n=335 in the exercise plus education group, n=290 in education-only group; figure). The proportion of women who did not participate due to family or husband refusal in the exercise plus education group was higher than the proportion in the education-only group. Furthermore, 46 women were excluded after consenting due to being too far from the centre of the village, leaving 298 in the exercise plus education group and 281 in the education-only group. Baseline characteristics for participants that might affect the outcome are shown in table 1; the groups were similar in all these characteristics. We also recorded whether women were receiving ongoing treatment for diabetes, but only 25 (n=15 exercise plus education group, n=10 education-only group) were receiving such treatment. The 24-week follow-up period in the final village was completed on July 2, 2018.

All 32 villages completed the intervention and are included in the analysis. The number of women in each village ranged from 12 to 27, with a median of 17 women per village (IQR 15–20). The ICC at baseline for the primary outcome (urinary leakage) was 0.74. High correlation was seen between responses on the Bangla version of the UDI short form* and the number of knots at baseline (data not shown). Few women (15 [5%] in the exercise villages, seven [2%] in the education villages) did not provide a 3-day continence record at week 24. Results of the unadjusted difference-of-differences analyses are shown in table 2 and the adjusted multilevel model-based evaluation are shown in table 3. Baseline scores for the primary outcome differed between the intervention groups, with those in exercise plus education villages having more leakage episodes over 3 days at baseline (difference 1.26 episodes, 95% CI 0.36–2.16). Those in the exercise plus education group had significantly lower leakage scores at 6 months than those allocated to the education-only group, estimated by the

---

### Table 1: Baseline characteristics by village and participants

| Characteristic                      | Exercise plus education group (n=16) | Education-only group (n=16) |
|-------------------------------------|-------------------------------------|----------------------------|
| Village (n=16) Women (n=298)        | Village (n=16) Women (n=281)        |
| Age, years                          | 64.5 (1.2)                          | 64.7 (1.3)                  |
| Body-mass index                     | 20.9 (1.2)                          | 20.7 (2.1)                  |
| Gravidity                           | 6.8 (1.2)                           | 6.9 (1.5)                  |
| Poor or very poor                   | 69.0%                               | 63.1%                      |
| Widowed                             | 38.0%                               | 42.2%                      |
| Living in younger generation’s household | 44.3%                               | 48.0%                      |

Data are mean (SD), mean proportion, and n (%). For villages, means of proportions for all villages in the cluster are given.

---

### Table 2: Baseline and 24-week outcome data by intervention group

| Outcome                          | Exercise plus education group (n=16) | Education-only group (n=16) | Exercise plus education versus education only |
|----------------------------------|-------------------------------------|----------------------------|-----------------------------------------------|
|                                  | Baseline 24 weeks Difference        | Baseline 24 weeks Difference |                                                |
| Primary outcome                  |                                      |                            |                                               |
| 3-day leakage episodes           | 12.6 (3.7)                          | 11.3 (4.7)                 | -10.8                                         |
| Secondary outcomes              |                                      |                            |                                                |
| Health state                     | 42.4 (9.3)                          | 42.2 (7.7)                 | -3.1                                          |
| Depression scale                 | 14.8 (3.9)                          | 15.0 (3.9)                 | -1.2                                          |
| EQ5D subscale                    |                                      |                            |                                                |
| Mobility                         | 14.8%                               | 23.0%                      | -2.3                                          |
| Self-care                        | 15.4%                               | 21.0%                      | -0.1                                          |
| Usual activities                 | 23.7%                               | 27.8%                      | -4.1                                          |
| Pain or discomfort               | 85.2%                               | 86.0%                      | -0.8                                          |
| Anxiety or depression            | 82.9%                               | 85.2%                      | -2.3                                          |

Data are mean (SD), mean proportion, mean difference, and percentage difference by village, and difference-of-differences analysis with 95% CIs in parentheses. For the EQ5D subscale, means of proportions for all villages in the cluster are given. The difference is 24 weeks minus baseline, and the difference-of-differences analysis is the difference of each group with exercise plus education minus education only.

---
difference-of-differences analysis (table 2) and by the random-effects model (table 3). The estimated difference from baseline to week 24 was similar when calculated by both approaches (data analysis for month-by-month analysis of number of leakage episodes is in the appendix). In a deviation from protocol, a different research paramedic served the two villages in four pairs of villages. We saw no difference in the primary outcome between the 12 pairs using the same research paramedic and the four using different paramedics for each village within the pair (data not shown).

For the secondary outcomes, both analytical approaches showed a larger improvement in heath state in the exercise plus education group than in the education-only group. Unlike the difference-of-differences analysis, the random-effects model showed a lower proportion of participants in the exercise plus education group reporting pain and discomfort at 24 weeks. Analysis of changes from baseline to 24 weeks showed that quality-of-life scores were higher overall (β 13.6, 95% CI 9.1 to 18.4) and depression scores lower (β –1.9, –3.3 to <-0.1) at 24 weeks than at baseline, but in a model including time, the improvement in depression score was not different after the intervention (table 3). The proportion of women who were cured (ie, with no leakages in the previous 3 days at 24 weeks) calculated by village gave a median of 41% (IQR 26–64) in the villages in the exercise plus education group and zero in the education-only group, where no women had any leakages at 24 weeks. The attributable proportion of participants cured was 41% (95% CI 27 to 62).

33 (11%) of 298 women in the 16 villages assigned to exercise plus education elected not to join the research paramedic-led exercise classes in weeks 13–24 (per-protocol population). By village, the proportion of participants who were per protocol ranged from 0% to 30% of those still participating in the study after 12 weeks. The post-hoc analysis of villages in which at least one woman elected to not join the classes in weeks 13–24 (per protocol) was limited to 11 pairs (post-hoc analysis population included all women from the 11 education-only villages, and one to seven women in the 11 exercise plus education villages). The random-effects model estimated an improvement of –5.3 (95% CI –7.9 to –2.6) in the number of episodes of urinary leakage. This difference was somewhat smaller than that reported in the multilevel model-based analysis (table 3) but suggested that those who elected to not join the research paramedic-led classes still improved their continence from the physiotherapist-led classes.

Analysis of the reasons for dropping out of the study showed that ten women in villages assigned to the exercise plus education group and seven in villages in the education-only group did not continue for the following reasons: they had died (n=2 exercise plus education group, n=1 education-only group), moved away (n=4 exercise plus education group), were with family outside the village (n=3 exercise plus education group, n=3 education-only group), could not be found (n=1 exercise plus education group), or no longer wished to take part (n=3 education-only group). Additionally, five women in villages in the exercise plus education group were recorded as stopping because of ill health; none of the medical conditions reported were associated with exercise class participation. No adverse events were reported.

Discussion

In this study, we found that a group exercise programme, supplemented with a home exercise plan, over 24 weeks was successful in decreasing urinary incontinence and increasing dryness in women. Analysis of secondary outcomes showed improvement in both intervention groups in the quality-of-life and depression scales at 24 weeks, but with more improvement in quality of life in the group that included the group exercise classes. Women in this group were also less likely to report pain or discomfort at the end of the trial, but this trend was only seen in the multilevel model-based analysis. The exercise intervention, comprising pelvic floor muscle and musculoskeletal exercise, was successfully delivered in rural locations with limited resources, with no reports of adverse events. The results reported here are consistent with the recent Cochrane meta-analysis,2 with 41% of participants in the exercise plus education villages being dry at 24 weeks. The improvement in quality of life by use of the EQ5D visual analogue scale is somewhat unexpected, with previously reported positive results being confined to symptom-specific quality-of-life questionnaires.2

This exercise intervention differs in two respects from most PFMT programmes. First, the exercise therapy was
delivered in a group setting rather than one-on-one; a similar approach was reported in only four of the 31 trials included in the Cochrane meta-analysis. Second, the approach aimed to improve mobility as well as pelvic floor muscle strength. In the villages where these women live they have no indoor sanitation, hence poor mobility would be expected to increase the number of leakage episodes. Using a similar combination approach as we did here, Kim and colleagues reported 44% (26 of 59) of participants were cured after 12 weeks in women living in the community in Japan. A pilot trial in frail older women in the USA also showed a decrease in incontinence in a programme that included both PFMT and other conservative therapies and strength and gait training. To our knowledge, no trial has considered PFMT alone against PFMT plus strength and mobility training.

Strengths of this study include successful randomisation of clusters, with close similarity between groups in potential confounders at baseline and a high rate of completion. The belt and ribbon continence record was developed for this study and was used in our pre-test and a feasibility study. It proved acceptable to the participants and provided a permanent record of the number of leakage episodes and micturitions. Although data were not reported here, we found high correlation between responses on the Bangla version of the UDI short form and number of knots at baseline, providing some validation of the approach.

Limitations of the study include difficulty in maintaining close monitoring of the progress of the trial and ensuring compliance with the protocol. The day-to-day running of the study was done in Bangla, which is not spoken by the Canadian investigators, under the management of local investigators who had not previously been involved in a randomised trial and without extensive formal research training. This difficulty was anticipated and the trial was undertaken only after the pre-test period with an initial two-village test of the acceptability of the exercise programme, followed by a more formal five-village feasibility phase partly planned to maximise the flow of communication between the Bangladeshi and Canadian investigators. Although extensive training was not needed to lead the exercise groups (as might be done in a non-research context), the long run-in period was needed to ensure full understanding of the research method and the need to follow formal procedures.

The difficulty in maintaining close monitoring of the trial led to two deviations from protocol. First, approximately 6 months into the trial, we realised that the villages had been unmasked to their assigned intervention before obtaining consent, rather than after consent. This deviation from protocol arose from poor communication between the Canadian and Bangladeshi investigators, but given the need to negotiate an exercise location and the high proportion of women whose refusal to participate was triggered by family members, the ideal of disclosure after consent was probably impracticable. Discussion of ethical issues in cluster randomised trials accept that circumstances in which consent before randomisation is not practicable exist, and that consent after randomisation “is consistent with the moral purpose of informed consent”. However, knowledge of the intervention might result in differential consent, perhaps indicated in this study by a higher baseline number of leakages in those who consented to join the exercise plus education group than among those who consented to join the education-only group.

The second deviation from protocol was the introduction of research paramedic classes during weeks 13–24 in all villages assigned to the exercise plus education group. The effect of the research paramedic-led classes was explored in a post-hoc analysis that suggested that the original protocol would have produced similar, albeit slightly smaller effects, than those observed for the full study population. A more minor deviation was that a different research paramedic served the two villages within four village pairs. No difference was seen in the primary outcome between the 12 pairs using the same research paramedic and the four using different paramedics for each village within the pair (data not shown). Finally, in the first of 32 villages, some initial lack of understanding in the use of the belt is apparent, with very few recorded leakage episodes (despite high scores on the UDI short form) during the first 16 weeks, with the number of episodes recorded increasing thereafter. This village, which was in the education group, was the only one in which this pattern was seen. Data from this village have been included in the analysis and might have resulted in a slightly conservative estimate of intervention effect.

A further limitation is that the villages eligible for inclusion were those with good records from which to identify potentially eligible women and these might not have been typical of all villages served by Gonoshasthaya Kendra. Furthermore, villagers served by Gonoshasthaya Kendra might not be typical of all village dwellers in Bangladesh because they might have had better access to health care for many years. Additionally, field workers might have been able to build on this relationship to obtain good collaboration. Despite these special circumstances, these results would likely be generalisable to other communities with few resources in which physiotherapists are working with groups of older people in the community. Such situations might currently be rare, but the apparent success of the research paramedics in running the exercise groups in this study suggests that other paramedics could be trained to take on leadership and delivery of such exercise groups. This extension to less specialist health workers is being tested by Gonoshasthaya Kendra.

The results of this trial are analogous to those in wealthy societies (eg, Japan and the USA) and the Cochrane review of PFMT, including the smaller trials that used combination therapy. The innovation here is that, when incorporated with mobility exercises in a group setting, PFMT is possible and effective among some of the world’s least privileged
older women who would otherwise have little or no help in managing this distressing and pervasive condition.

Contributors
NC and AW designed the study and the content of the training camps and drafted the paper. YY oversaw the power calculations. NC and J-MG carried out the analyses, with issues resolved by YY. RH and FK ran the project in the field, with FK and NC responsible for the coding, data entry, and data quality. ZC contributed to the conception of the trial, development of the field, with FK and NC responsible for the coding, data entry, and data quality. ZC contributed to the conception of the trial, development of the field, with FK and NC responsible for the coding, data entry, and data quality. NC and KN devised the exercise intervention, with KN taking responsibility for the team of physiotherapists in the field. All authors contributed to the drafting and critical review of the manuscript.

Declaration of interests
We declare no competing interests.

Data sharing
The authors will make all data available to scientists planning meta-analyses or to conduct specified and agreed further analyses. For access, please contact the corresponding author.

Acknowledgments
This study was funded by the Canadian Institutes for Health Research.

References
1. Simms, J., Browning C., Lundgren-Lindquist B., Kendig H. Urinary incontinence in a community sample of older adults: prevalence and impact on quality of life. *Disabil Rehabil* 2011; 33: 1389–98.
2. Dumoulin C., Cacciarri L.P., Hay-Smith E.J.C. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev* 2018; 10: CD000564.
3. Cherry N., Chowdhury, M., Haque R., McDonald C., Chowdhury Z. Disability among elderly rural villagers: report of a survey from Gonoshasthaya Kendra, Bangladesh. *BMJ Public Health* 2012; 12: 379.
4. NICE Urinary incontinence and pelvic organ prolapse in women: management. NICE guideline [NG123]. April, 2019. https://www.nice.org.uk/guidance/ng123 (accessed April 29, 2019).
5. Namdar AK, Bosch R, Cruz F, et al. EAU guidelines on assessment and nonsurgical management of urinary incontinence. *Eur Urol* 2018; 73: 596–609.
6. Robert M., Ross S. No. 186-Conservative management of urinary incontinence. *J Obstet Gynecol Can* 2018; 40: e119–25.
7. Kumar S., Jain V., Mandal A., Singh A. Behavioral therapy for urinary incontinence in India. *Int J Gynaecol Obstet* 2008; 103: 125–30.
8. Jirovec MM. The impact of daily exercise on the mobility, balance and urine control of cognitively impaired nursing home residents. *Int J Nurs Stud* 1991; 28: 145–51.
9. Bates-Jensen B., Alessi C., Al-Sammarai N., Schnelle J. The effects of an exercise and incontinence intervention on skin health outcomes in nursing home residents. *J Am Geriatr Soc* 2003; 51: 348–55.
10. Ouslander J., Griffiths P., McConnell E., Riolo L., Kutner M., Schnelle J. Functional incidental training: applicability and feasibility in the Veterans Affairs nursing home patient population. *J Am Med Dir Assoc* 2005; 6: 121–22.
11. van Houten P., Achterberg W., Ribbe M. Urinary incontinence in disabled elderly women: a randomized clinical trial on the effect of training mobility and toileting skills to achieve independent toileting. *Gerontology* 2007; 53: 205–10.
12. Sugaya K., Nishijima S., Owan T., Oda M., Miyazato M., Ogawa Y. Effects of walking exercise on nocturia in the elderly. *Biomed Res* 2007; 28: 301–05.
13. Morrison RN, Rodriguez IV, Wang PC, Smith AL, Tiejo L, Sarkissian C. Correlates of 1-year incidence of urinary incontinence in older Latino adults enrolled in a community-based physical activity trial. *J Am Geriatr Soc* 2014; 62: 740–46.
14. Kim H., Yoshida H., Suzuki T. The effects of multidimensional exercise treatment on community-dwelling elderly Japanese women with stress, urge, and mixed urinary incontinence: a randomized controlled trial. *Int J Nurs Stud* 2011; 48: 1655–72.
15. Kim H., Yoshida H., Suzuki T. Effectiveness of multidimensional exercises for the treatment of stress urinary incontinence in elderly community-dwelling Japanese women: a randomised, controlled, crossover trial. *J Am Geriatr Soc* 2007; 55: 1932–39.
16. Lemack G., Zimmern P. Predictability of urodynamic findings based on the Urogenital Distress Inventory-6 questionnaire. *Urology* 1999; 54: 461–66.
17. Medical Research Council. Cluster randomized trials: methodological and ethical considerations. MRC trials series. London: Medical Research Council, 2002. https://www.cebm.nhs.uk/wp-content/uploads/Cluster-randomised-trials-Methodological-and-ethical-considerations.pdf (accessed April 29, 2019).
18. Wagg A., Cherry N., MacDonald D., et al. Development and testing of a continence record for use with illiterate older women in rural Bangladesh. *Neurourol Urodyn* 2015; 34 (suppl 3): S208–09.
19. EuroQol Group. EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy* 1990; 16: 199–208.
20. Andersen EM, Malmgren JA, Carter WB, Patrick DL. Screening for depression in well older adults: evaluation of a short form of the CES-D (Center for Epidemiologic Studies Depression Scale). *Am J Prev Med* 1994; 10: 77–84.
21. Donner A., Bickett N., Buck C. Randomization by cluster. Sample size requirements and analysis. *Am J Epidemiol* 1983; 114: 906–14.
22. Diehr P., Martin DC, Koepsell T., Cheadle A. Breaking the matches in a paired t-test for community interventions when the number of pairs is small. *Stat Med* 1995; 14: 1491–504.
23. Hooper R., Frobes A., Hemming K., Takeda A., Beresford L., Analysis of cluster randomised trials with an assessment of outcome at baseline. *BMJ* 2018; 360: k1121.
24. Talley KMC, Wyman JF, Bronas U., Olson-Kellogg BJ, McCarthy TC. Defeating urinary incontinence with exercise training: results of a pilot study in frail older women. *J Am Geriatr Soc* 2017; 65: 1321–27.
25. Weijer C., Grimshaw J., Eccles M., et al. The Ottawa statement on the ethical design and conduct of cluster randomized trials. *PLoS Med* 2012; 9: e1001346.
26. McAteer AD, Weijer C., Binik A., et al. When is informed consent required in cluster randomized trials in health research? *Trials* 2011; 12: 202.