

CLINICAL TRIALS DON'T JUST HAPPEN: STEPS TO INITIATE AN EXERCISE TRIAL TO MANAGE INCONTINENCE IN ELDERLY, ILLITERATE, VILLAGE WOMEN

Hypothesis / aims of study

A needs assessment among 43,417 men and women aged 60 years or greater living in 535 villages in rural Bangladesh found that 26% of men and 30% of women reported urinary incontinence with 41% of those with incontinence also reporting depression, compared to 15% without [1]. Urinary incontinence was more strongly related to over-all disability than any health problem except hemiplegia. Health care in these villages was the responsibility of a single Non-Governmental Organization (NGO) which had recently instituted a community physiotherapy service to supplement the home and health centre care provided by a largely female field force of paramedics, trained to work in the villages. In discussion with the NGO it was agreed that an exercise-based intervention, building on the work of Kim et al [2], lead by the community physiotherapists and supported by the village paramedic, would be a feasible way of helping to manage distressing incontinence. Further, if preliminary work supported it, this intervention should be evaluated through a cluster randomized trial. The three studies reported here reflect the extent of preparatory work needed to convince both the research team and the funding body that it was feasible to carry out a full 4 year trial of a six month exercise-based intervention amongst elderly village women, >90% of whom are illiterate.

Study design, materials and methods

Study 1 was designed to test the quality of translation, acceptability and test-retest characteristics of the research instruments chosen for the study, including the 2-item Sandvik Severity Index, the 6 item urinary distress inventory (UDI v6 SF), the EQ-5D and a 7 item Geriatric Depression Scale. The questionnaires were translated and back-translated (except for the EQ-5D, which existed in a Bangla form) and tested through oral administration by graduate students of a local university. Thirty village women aged 60-75 years completed the scales twice with a four week interval.

Study 2 was designed to test the viability and acceptability of the exercise regimen. This was devised in collaboration with the local community physiotherapists, starting from the approach used in Canada by the lead Canadian physiotherapist. The frequency of group exercise was based on the intervention reported by Kim et al [2] who used group exercise twice weekly for 12 weeks followed by 12 weeks of only home exercise. To test this regimen a 4 week pre-test was conducted, with 8 women village women attending 8 exercise classes under the supervision of local community physiotherapists. The women also completed the baseline and follow-up evaluation amended in the light of study 1 and completed pre- and post intervention 3 day continence records especially devised for the low literacy population.

Study 3 was a feasibility study involving 4 intervention and one control village. This had three goals 1) to identify and resolve any difficulty with the implementation of the full six month intervention 2) to inform sample size calculations for the full trial and 3) to build capacity within the local research team. Semi-structured interviews in Bangla were conducted by female graduate students with those who refused to take part in the study or who dropped out and with a sample of those who completed all six months of the study. These interviews (translated to English), and insights from a post intervention retreat, were summarized by a senior faculty member from a local university.

Results

In study 1 there was a high test-retest correlation (0.9) for the Sandvik Index with test-retest on individual items on the UDI ranging from 0.75-0.93. On the EQ-5D, Cronbach's alpha was 0.78 at baseline. Interviewer misunderstanding on completion of the depression scale (since replaced) limited the usefulness of this part of the pre-test but the test-retest on a question 'are you basically happy with life' was 0.82.

Study 2 indicated that the exercise intervention was acceptable without modification, and that the paramedics and the community physiotherapists understood, and could collect and record, the necessary administrative data.

The results from study 3 were essential for planning the full trial. Women were recruited from 5 villages including one acting as a 'control' (assigned rather than randomized) in which women did not undergo exercise training but completed the baseline and end of study questionnaires and a monthly continence record. Lists of potentially eligible women (regardless of incontinence) were drawn up from participants (essentially all female village residents aged 60 years or greater) in the 2009-10 disability survey [1], giving a target of 139 women. Eight were found to have died and one was paralyzed. A total of 17 women were recorded as refusals, 7 being forbidden by a male relative, 6 refused because of religious barriers and 4 refused from their own choice. Thirty four were not found, disproportionately from the first village where the necessity to visit everyone was not fully understood. The response rate among those believed to be alive and eligible overall was 61% (79/130) or 82% (79/96) of those contacted. In each village some additional eligible women, not on the initial lists, volunteered for the study giving a total number of participants of 122, including 29 in the control village. Of these 98 completed the final (6 month) assessment. In the intervention villages the median number of exercise classes attended was 17 (from a possible total of 24).

Calculation of sample size for the full study depended on estimates of intraclass correlation and likely effect size, based on changes in the three day continence record, devised for the study, and on the health scale of the EQ-5D. The proportion recording no involuntary leakage increased from 32% at baseline to 45% at exit, while the score on EQ-5D improved from 5.8 to 6.7.

Feedback from the qualitative assessment suggested that women who dropped out felt cheated at being offered only exercise and not medication, and that they found it difficult to have the exercise supervised by young women, not in traditional dress, who were the same age as their granddaughters. Very few women who dropped out gave physical or psychological discomfort as a reason.

Interpretation of results

The results of the three studies suggest that the intervention was viable and that the village women and the local team understood and accepted all that the study involved. Some changes to the design have since been made, most importantly restricting recruitment to those incontinent at baseline.

Concluding message

Little is known about the effectiveness of exercise-based interventions in rural parts of the developing world, but incontinence there is widespread and distressing. Demonstration, through a cluster randomized trial, that exercise-based interventions could help manage incontinence in such women at very little cost and without sophisticated equipment or technology, would open the door to a greatly improved quality of life for incontinent women in poor communities worldwide.

References

1. Cherry N Chowdhury CHaque R et al. BMC Public Health, 2012; 12:379
2. Kim H Yoshida H Suzuki T. Int J Nurs Stud 2011 48: 1165-72

Disclosures

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