A PHASE II EXPLORATORY CLUSTER RANDOMISED CONTROLLED TRIAL (RCT) OF A GROUP MOBILITY TRAINING AND STAFF EDUCATION INTERVENTION TO PROMOTE URINARY CONTINENCE IN UK CARE HOMES

Hypothesis / aims of study
To assess feasibility, acceptability and potential efficacy of group exercise and staff education intervention to promote continence in older people residing in care homes. To establish measures and information to inform a larger trial.

Study design, materials and methods
Design: Phase II pilot exploratory cluster randomised controlled trial.
Setting: Six purposively selected care homes in the (area removed), UK.
Subjects: Thirty-four care home residents (mean age 86, 29 female), 23 with cognitive impairments.
Intervention: Physiotherapy led group exercise and staff continence and mobility facilitation training.
Main outcome measures: Reported continence status, Rivermead Mobility Index (RMI). Feasibility was assessed by uptake and compliance, and acceptability by verbal feedback. A staff knowledge questionnaire was used.

Results
33 residents, cluster sizes from 3 to 7. The number of residents agreeing with the statement ‘Do you ever leak any urine when you don’t mean to?’ in the intervention group decreased from 12/17 at baseline to 7/17 at 6 weeks in the intervention group and increased from 9/16 at baseline to 9/15 at 6 weeks. The RMI scores were better in the intervention group (n=17; baseline: 6.1, 6 weeks: 6.2) compared with controls (n=16; baseline: 5.9, 6 weeks: 4.75).

Interpretation of results
The intervention was feasible, well received and had good compliance. Dependent on the choice of design, a definitive trial would require a sample size of at least 686 residents, 78 homes.

Concluding message
Group mobility training and staff education to promote continence is feasible and acceptable for use with care home residents including those with cognitive impairment

Specify source of funding or grant | Research into Ageing, NIHR career scientists
Is this a clinical trial? | Yes
Is this study registered in a public clinical trials registry? | No
What were the subjects in the study? | HUMAN
Was this study approved by an ethics committee? | Yes
Specify Name of Ethics Committee | South Birmingham PCT
Was the Declaration of Helsinki followed? | Yes
Was informed consent obtained from the patients? | Yes