Balance Right in Multiple Sclerosis (BRiMS): A guided self-management programme to reduce falls and improve quality of life, balance and mobility in people with secondary progressive multiple sclerosis: a protocol for a feasibility randomised controlled trial

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Balance Right in Multiple Sclerosis (BRiMS): A guided self-management programme to reduce falls and improve quality of life, balance and mobility in people with secondary progressive multiple sclerosis: a protocol for a feasibility randomised controlled trial

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Background:
Impaired mobility is a cardinal feature of multiple sclerosis (MS). By the secondary progressive phase, balance, mobility and physical activity levels are significantly compromised; an estimated 70% of people with secondary progressive MS fall regularly. Our ongoing research has systematically developed ‘Balance Right in MS’ (BRiMS), an innovative, manualised 13-week safe mobility and falls self-management programme tailored to the needs of people with MS. Our eventual aim
is to assess the clinical and cost effectiveness of BRiMS via a fully powered, multicentre, assessor-blinded randomised controlled trial (RCT). This feasibility study will assess the acceptability of the intervention and achievability of running such a trial.

**Methods/ Design:** This is a pragmatic multi-centre feasibility RCT with blinded outcome assessment. Sixty ambulant people with secondary progressive MS who self-report two or more falls in the previous six months will be randomly allocated 1:1 to either the BRiMS programme plus usual care or to usual care alone. All participants will be assessed at baseline and followed up at 15 weeks and 27 weeks post randomisation.

**Outcomes:**
- Feasibility outcomes, including recruitment, retention and completion
- Assessment of the proposed outcome measures for the anticipated definitive trial (including measures of walking, quality of life, falls, balance and activity level)
- Measures of adherence to the BRiMS programme
- Data to inform the economic evaluation in a future trial
- Process evaluation (assessment of treatment fidelity and qualitative evaluation of participant and treating therapist experience).

**Conclusion:**
The BRiMS intervention addresses an issue which is a key concern for MS service users and providers. This feasibility trial will provide important insights into the acceptability of the BRiMS intervention and the practicality of running a full-scale trial, and will enable a protocol to be finalised for use in the definitive trial.

**Trial Registration:** ISRCTN13587999