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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