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ExIMS Trial:

Overview and Lessons Learnt

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Rationale

- Supervised, 1-to-1, facility-based exercise can be beneficial (Reitberg et al., 2005; Heeson et al., 2006; Dalgas et al., 2008)
- Long-term this may be difficult for PwMS and is unlikely to be cost-effective
- Need for more high quality RCTs, offering MS-tailored interventions, providing evidence to guide regular exercise prescription (Asano et al., 2009)
- Need for information on exercise dose to achieve optimal benefit (Reitberg et al 2005)
- Need to assess efficacy of a pragmatic, tailored and cost-effective approach




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Research Question

Can a pragmatically-designed exercise intervention evoke improvements in physical activity, function and health in PwMS?

Is this a cost effective treatment strategy?

Secondary Objectives:

- What dose of exercise is achievable?
- Do dose-response relationships between physical activity and health outcomes exist for PwMS (with different disability levels)?
- Impact of disease severity on response to intervention

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Study Design

Flow Chart

Baseline Assessment (0-months)

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Group Randomisation
(Stratified for disease severity, age and gender)

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Exercise Group:

Weeks 1-6
2 x week supervised exercise at University
1 x week exercise at home

Weeks 7-12
1 x week supervised exercise at University
2 x week exercise at home

Usual Care:

Weeks 1-12
Continue with usual support for 12 weeks

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Follow-up Assessment (3-months)
(Random sample of exercise group take part in 1-to-1 interviews and focus groups)

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Interviews and Focus Groups

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Follow-up Assessment (9-months)

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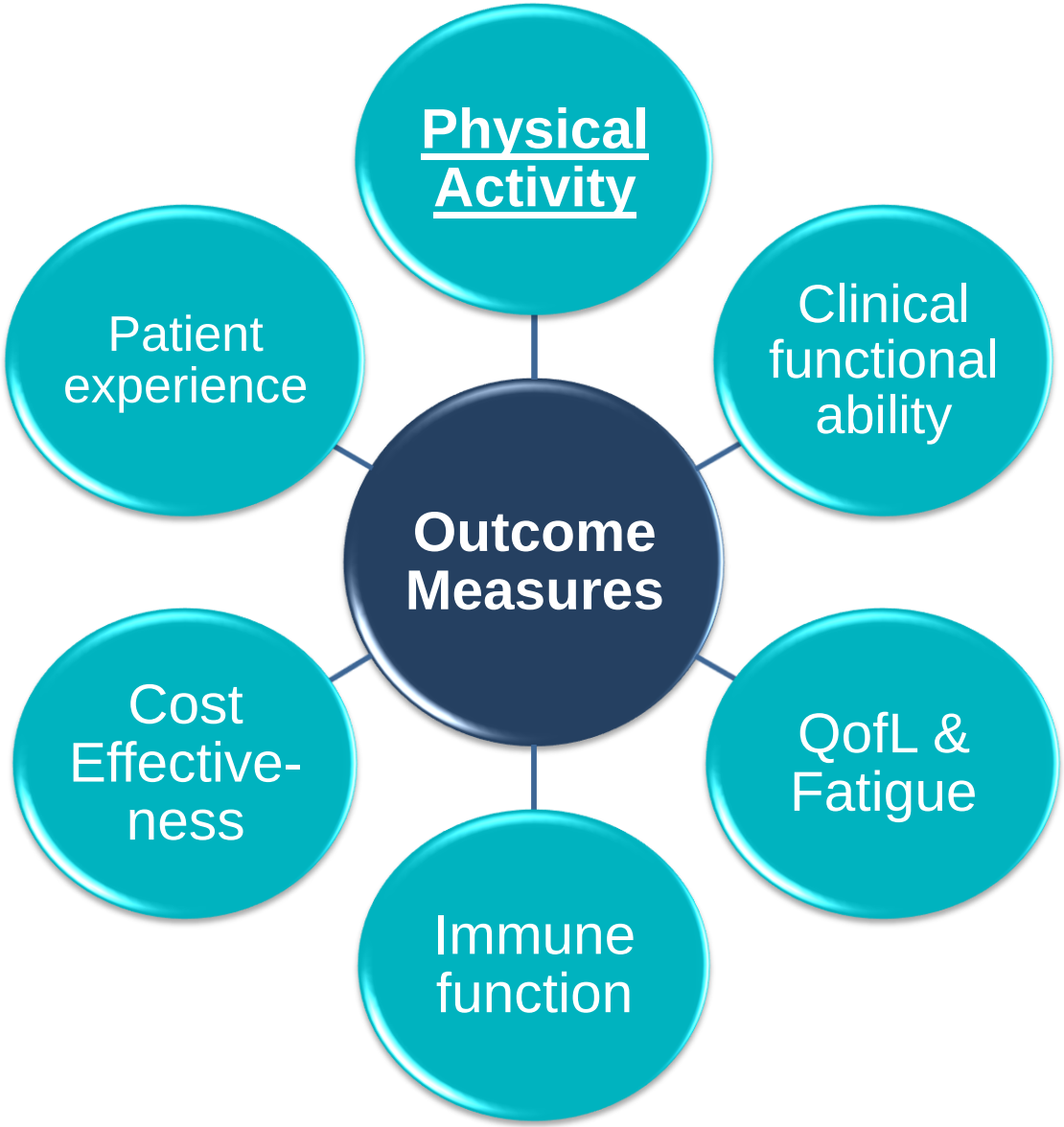
Study Design

Outcome Measures



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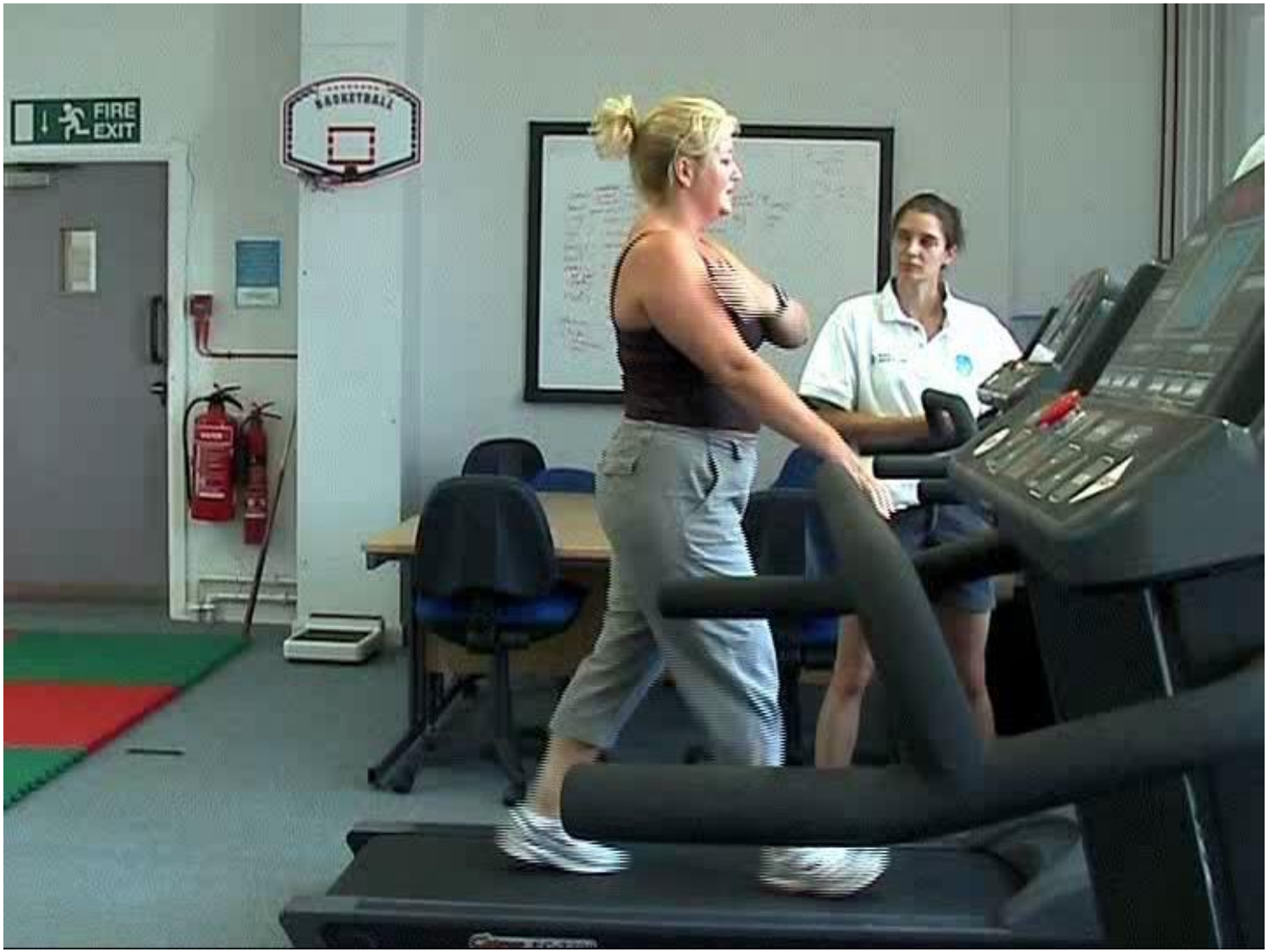
So what did we do?

Typical exercise session



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What did the exercise professionals do?

1. Initial assessment

- Current activity levels
- Exercise preferences
- Exercise goals
- Equipment and facilities available
- MS signs and symptoms

2. Introduced and progressed aerobic activity and general strengthening work

- Each new activity tried for only 2 minutes
- Heart rate and Borg monitored 2/3 times during each activity
- Borg kept between 11 – 14
- Heart rate (HR) kept within 50 – 69% of predicted HR max (220 – age)

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What did the exercise professionals do?

3. Support and motivation

- Goal setting
- Finding support and facilities
- Promoted understanding of benefits and costs of exercise
- Promoted achievable changes in behaviour
- Promoted sustainable levels of activity

4. Action planning for the future – for after the trial

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What did the physiotherapist do?

1. Advice on **safe exercise** – what aerobic activities to avoid
2. 20% of participants required advice on **musculoskeletal problems** that arose before or during the exercise programme (knee, neck, shoulder, hip, thoracic or lumbar spine)
3. 5% had **orthotics** reviewed – to allow an increase in activity
4. Many had **walking aid advice** related to exercise progression
5. Three required advice on **anti-spasmodic management**
6. 73% of participants had **physiotherapist prescribed exercises** in addition to general exercise aimed at addressing specific movement problems

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What did the physiotherapist do (1)?

Exercise category	Aimed to improve	Examples of exercises	
Balance	Head stabilisation	Looking in the mirror – turning head without moving eyes, turning/swaying body without moving head.	7%
Balance	Whole body control in single leg stance/stepping	Single leg stance, knee lifts, "clock face".	23%
Hip stability and control	Wide based gait or poor lateral control in stance phase	Rocker board side-to-side, Profitter, Theraband for abduction/adduction.	30%
Lower limb stability and control	Weight-bearing asymmetry or flexed knees or knees give way	Sit-to-stand, squats, theraband, step-ups, quads bench (leg press).	34%

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What did the physiotherapist do (2)?

Exercise category	Aimed to improve	Examples of exercises	
Hip stability and control	Anterior tilted pelvis or altered hip alignment	Rocker board, posture exercises, gym ball activities.	16%
Trunk exercises	Poor scapula control, ataxic trunk, altered trunk alignment	Gym ball activities, Theraband/upper limb in sitting, crook lying exercises.	64%
Graded weight bearing	Managing increased tone	Standing, leaning, lateral weight-transfer, trunk movement in perch sitting	20%
Stretches	Loss of joint or muscle range	Thoracic extension, hip flexor stretch, hamstring stretch	18%
Upper limb exercises	Intrinsic muscle control, shoulder exercises	Manipulating objects, handwriting practice, shoulder exercises in supine.	7%

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Results

Adherence to intervention

	Supervised (Sessions -max 18)	Supervised (%)	Home (Sessions - max 18)	Home (%)
All n=60 (6 did not complete)	16.2	90	14.6	81
Low 1.0-2.5 n=29 (all completed)	16.5	91.4	14.8	82.3
Medium 3.0-4.5 n=24 (1 did not complete)	15.9	88.2	13.8	76.4
High 5.0-6.5 n=7 (5 did not complete)	13.7	75.9	8.7	48.1

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Results

Quantitative

	Follow-up 1 (3-months)	FU2 (9-months)
Physical Activity • GLTEQ	↑ (p = 0.01)	↑ (p = 0.08)
Daily Step Count • Accelerometer	↑ (p=0.009)	__
Fatigue • MFIS	↑ (p = <0.0001, all domains)	__
Quality of Life • MSQol-54	↑ (most domains)	↑ (emotional wellbeing Social function overall QoL)
Clinical Functional Ability • MSFC • EDSS	__	__

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Results

Qualitative

Overall themes

- Health professionals could do more to endorse the importance of exercise - previous advice lacked specificity.
- Exercise required commitment - maintaining activity levels was challenging
- Exercise was rewarding

I think with any illness you want someone to say to you “if you do this or don't do this or the other it will help or it'll be worse”. What I don't want to do is anything that will make it worse

.. you were scared about doing the wrong thing - so you did nothing ..

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Results

Qualitative

I still get tired but I think that I recover faster.

Study changed perception of ability

- Recover more quickly
- Know that they can improve with exercise
- Sleeping better
- Various physical benefits

I'm feeling quite positive about things and much more able to do things. So whether or not it was MS that was making me tired, or my general low level of fitness, which has now improved, I don't know. But it's been better

just doing that little bit made me feel better because I could say to myself I'd done something and that the fatigue hadn't beaten me…

Well for me, what it's done, having done this course, it's built my confidence up and it's proof to myself that I can do, rather than sitting in the car sobbing thinking I can't do. I can do it. I can do it at my weight and my length of time and my choice of how many days a week

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Results

Cost Effectiveness

Average intervention cost per person = £375

$$\text{Incremental Cost Effectiveness Ratio (ICER)} = \frac{\text{Costs incurred by treatment group} - \text{Costs incurred by control group}}{\text{Change in treatment group (QALYs)} - \text{Change in control group (QALYs)}}$$

An “acceptable ICER” is estimated between £20,000 - £30,000 per Quality Adjusted Life Year (QALY).

Our cost per QALY was £10,137.

In the more severely affected (EDSS ≥4), the intervention was more cost-effective at £5092 per QALY.

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Future development needs

Improving adherence after a course of supervised exercise

Some sort of reporting system may help adherence:

- Pre-planned review sessions:
  - either just showing an interest
  - or actually assessing key outcomes and abilities
  - or reviewing an activity diary
- An “App” on which you log your exercise activity; particularly if someone real actually checks your “App”!
- A buddy system – reporting your activity levels to a friend who is also working towards the same goals

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Future development needs
Changing working systems to improve exercise behaviours

- Therapists broaden their remit and their knowledge of local facilities to facilitate regular activity?
- Redesign to bridge into improving healthy lifestyles?
  - Use exercise professionals more within NHS services?
  - Upskill existing healthcare staff?
  - Employ "bridging staff" employed by health but able to take participants into community services to introduce, induct, empower, review
- Don't just provide an exercise group! The aim is sustainable, achievable, behaviour change.

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Future development needs

Exercise options for more disabled people

- Most exercise studies have participants with EDSS (0 and 6.5)
- PwMS who have greater disability may be profoundly sedentary and have difficulty sustaining optimal levels of activity (Cavanaugh et al., 2011)
- Small increases in activity could have positive impacts on physical and mental health
- Challenge now is to explore the type of physical activity interventions that would be acceptable and achievable (current qualitative study)
- Upper body aerobic interval training is feasible (EDSS 6.0-8.0) - Skjerbaek et al., 2014

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Future development needs

High intensity exercise - is it safe?

High intensity interval training (HIIT) may be a potent therapeutic intervention to improve physical fitness and body composition.

The utility of HIIT for improving disease outcomes has been demonstrated in patients with diabetes, metabolic syndrome, heart failure, and chronic obstructive pulmonary disease.

Growing evidence suggests that this type of exercise stimulates physiological remodelling comparable with continuous moderate intensity training despite a lower time commitment.

These findings are important as people with MS are involved in fewer recreational activities than the general population.

Sub group analysis from current research suggests that participants with an EDSS 1.0-2.5, were able and wanting to do higher intensity exercise.

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Future development needs

Early intervention

- People diagnosed with MS are often scared to continue their normal exercise routine and become more sedentary than the general population
- This leads to deconditioning and an uphill struggle back to fitness
- Early exercise advice soon after diagnosis could help people to continue to better maintain and adapt their current exercise habits

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EXIMS

Take home messages

- We should be maximising people's understanding of and engagement with physical activity
- PwMS need to learn from experience that exercise works. To do this effectively:
  - progress slowly,
  - warn them that they might get worse in the short-term
  - and work with them for at least 12 weeks
- If you work with people at the point of diagnosis, try including detailed education really early on

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Questions

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