ENGAGE HD: A randomised controlled feasibility trial of a physical activity behaviour change intervention in HD.

Dr Cheney Drew
HD as a model disorder: Apathy?
Focus groups with HD patients/carers

Theme 1: Personal belief systems and motives
- prior attitudes
- value of exercise

Theme 2: Challenges
- disease specific factors affecting exercise
- social and physical environment

Theme 3: Enablers
- adaptive strategies
- personalised, expert approach
- patience, encouragement and support

Competence
- Perceived self-belief
- Goal-setting
- Positive Reinforcement
- Skill-Specific Feedback

Autonomy
- Freedom of choice
- Offer choice
- Redefine what exercise means

Relatedness
- Sense of shared experience
- Listen
- Respond to personal needs

College of Biomedical and Life Sciences
2.3 Tandem Standing

**Purpose:** This exercise will improve your standing balance and your balance during walking.

**Key points:** Place one foot in front of the other. If you can, put the heel of your front foot against the toe of your other foot. If you are unable to keep your balance in this position, put your front foot to the side but as close to the other foot as is comfortable. If you feel comfortable in this position, let go of the support while keeping your hand nearby.
**Logic Model**

**Outputs**

**Behavioural change**
Increased and sustained regular physical activity
Greater exercise related self-efficacy

**Behavioural outcomes**
Exercise specific skill development
Realistic goal setting and review
Improved self monitoring of physical activity (pedometers, exercise diaries, goal review, progression of exercise)
Competent use of exercise equipment and DVD

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**Immediate outcomes**
Increase in daily physical activity (IPAQ)
Stability of disease specific measures (UHDRS mMSE, Cognitive)
Stability of functional measures (UHDRS Function)
Improvement in self-efficacy measures (Lorig scale)
Improvement in health-related QoL (EQ-5D)

**Longer term outcomes**
Sustained physical activity behaviours
Longer term stability of disease measures and function
Longer term health benefits of regular physical activity
### Intervention Fidelity

Intervention fidelity assessed through coach-completed checklists and analysis of audio recordings of sessions.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Score</th>
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<tbody>
<tr>
<td>1. Autonomy</td>
<td>- Involves participants in decision making</td>
<td>Not at all</td>
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<td></td>
<td>- Minimizes control and pressure</td>
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<td></td>
<td>- Maximizes participants' choices</td>
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<td></td>
<td>- Provides a rationale for suggestions</td>
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<td></td>
<td>- Allows the participant to overtly express the pros and cons of changing behavior</td>
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<td>- Tailors advice and support</td>
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<td>2. Relatedness</td>
<td>- Acts in a warm and caring way</td>
<td>Not at all</td>
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<td></td>
<td>- Expresses empathy</td>
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<td>- Acknowledges and supports patients' perspectives, feelings, and values</td>
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<td></td>
<td>- Avoids judgment or blame</td>
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<td>3. Competence</td>
<td>- Helps to clarify outcome expectations (what a person might expect as result of the changes that they have made)</td>
<td>Not at all</td>
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<td></td>
<td>- Assists in realistic goal-setting and developing a tailored activity plan</td>
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<td></td>
<td>- Assists in building skills and developing coping strategies required to achieve specific goals</td>
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<td>- Provides positive feedback</td>
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<td>4. General impression</td>
<td>Overall perception of participant/coach interaction is positive</td>
<td>Not at all</td>
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<td></td>
<td>- Coach is in command of the session and demonstrates ability to direct conversation and maintain focus</td>
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Mean (SD) intervention fidelity scores (n=15) was 11 (2.4) (out of 16 possible points).
Study Protocol

Supporting physical activity engagement in people with Huntington's disease (ENGAGE-HD): study protocol for a randomized controlled feasibility trial

Monica Busse, Lori Quinn, Helen Dawes, Carys Jones, Mark Kelton, Vincent Polle, Rob Trubey, Julia Townsend, Rhiannon Tudor Edwards, Anne Rosser and Kerenza Hood

Abstract
Background: Huntington's disease (HD) is a complex, single-gene inherited neurodegenerative condition resulting in symptoms that occur across a wide range of neurological domains, including cognitive, behavioral and motor. The benefits of regular physical activity for people with HD are widely recognized. However, a number of factors can prohibit sustained exercise and activity. The purpose of this trial is to explore the feasibility, acceptability and effectiveness of a physical activity intervention program targeted for people with early- to mid-stage HD.

Methods/Design: The proposed trial is a single blind, multisite, exploratory, randomized controlled feasibility trial of a physical activity intervention. A total of 62 participants with genetically confirmed HD will be recruited. Each participant will be involved in the trial for 26 weeks. Participants will be randomized immediately following the baseline assessment into either a physical activity intervention or a social contact control intervention. The physical activity intervention is framed around self-determination theory placed within a broader behaviour change wheel framework. An HD-specific workbook and individual goal setting will be utilized over six 1:1 sessions, with interim telephone calls. All participants will be reassessed at 16 weeks following the baseline assessment, and then again at a final follow-up assessment 26 weeks later. At the end of the study, all participants will be offered a brief version of the alternative intervention, with one home visit and one follow-up telephone call.

Discussion: Engaging and supporting people with HD in a regular physical activity program raises a number of challenges. The physical activity intervention and the comparator social interaction intervention have been developed following consultation with people with HD and their families. Each is individually tailored and determined on individual needs and goals. The results from this trial will provide guidance for the development of definitive trials.

Trial registration: The trial was registered with ISRCTN (https://www.isrctn.com/ISRCTN65378754) on 13 March 2014.

Keywords: Huntington's disease, Physical activity, Randomized controlled feasibility trial
Outcomes: Feasibility and Self Efficacy

**FEASIBILITY**

Feasibility was assessed on recruitment, retention and adherence according to pre-defined measures.

All feasibility measures were met.

**EXERCISE SELF EFFICACY**

Exercise self efficacy (Lorig sub-scale) was 1.63 points higher (95% CI: [0.48, 2.78]).
Self-reported Physical Activity (IPAQ) scores were 125% higher in the physical activity group (95% CI:[4%, 388%])
Life Space scores in physical activity group were 16 points higher than in the social group at assessment 2 (95% CI: [2,30])
Conclusions

CONCLUSIONS
A physical activity coaching intervention delivered in a home setting is:
• feasible in people with HD
• improves self efficacy and levels of physical activity
• Improves cognition
• Does not improve physical function.
• Intervention was acceptable to participants

NEXT STEPS
• Larger scale efficacy trial with modification
• Potential for expansion to other neurological disorders where exercise may be of benefit
Acknowledgements

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**Trial management group:** Monica Busse (CI), Lori Quinn, Mark Kelson, Rob Trubey, Kirsten McEwan, Carys Jones, Julia Townson, Helen Dawes, Rhiannon Tudor Edwards, Anne Rosser, Kerenza Hood

**Trial sites:** NHS Grampian, Birmingham and Solihull Mental Health NHS Foundation Trust, North Staffordshire Combined NHS Healthcare Trust, Sheffield Children’s NHS Foundation Trust, North Bristol NHS Trust, University Hospital Southampton NHS Foundation Trust, Cardiff University, Central Manchester University Hospitals NHS Foundation Trust

**Trial Steering Committee:** Emma Stack (chair), Fiona Jones, Natalie Ives, Heather Thomas