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# Feasibility Meets Implementation Science: Narrowing the Research-To-Practice Gap for Exercise Activity in Multiple Sclerosis

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## Abstract

**Background:** There is a need to identify why multiple sclerosis exercise research is not translating into real-world participation. To lay the foundations of strong clinical research, considering the translational element of implementation science at the feasibility phase of a trial is vital. **Methods:** Document analysis was used to examine document sources on exercise activity interventions designed for people living with multiple sclerosis. Document sources focused on multiple sclerosis research that incorporated exercise prescription elements and behaviour change and were feasibility studies incorporating aspects of implementation science. **Results:** Implementation science should come much earlier than the efficacy or effectiveness research pipeline. An alternate view is outlined where feasibility and implementation science should meet based on case examples that have not yet shown strong efficacy or effectiveness. Findings from our key themes indicate a need for a cyclical iterative approach to the translational process. Multiple aspects of feasibility and how it can be assessed using an implementation science lens to support more successful interventions are provided. The determination of feasibility in behaviour change should involve implementation science as feasibility is drawn on for theory development, optimising the intervention design and quality of implementation strategies, and identifying those delivering the intervention before conducting efficacy and effectiveness research. **Conclusions:** Document analysis methodology is underused in qualitative research and was appropriate to use as it was a very resource, time-efficient and an unobtrusive process that could track change and development to explore the integration of implementation science at the feasibility phase, with the findings indicating the earlier implementation science is introduced into multiple sclerosis exercise interventions the better.

## Keywords

case study, qualitative evaluation, secondary data analysis, whole systems change, methods in qualitative inquiry

## Background

Multiple sclerosis (MS) is a disorder of the central nervous system (CNS) characterised by neural inflammation and destruction of myelin tissue, resulting in CNS scarring and inefficient neural activity (Dobson & Giovannoni, 2019). Exercise interventions improve health outcomes in people living with MS and other neurological conditions, and exercise, a subset of physical activity, is considered the single most effective non-pharmacological symptomatic treatment for MS (Dalgas et al., 2019; Learmonth & Motl, 2021). Evidence from Randomised Controlled Trials (RCTs) has been evaluated, and guidelines for minimal levels of exercise for persons with mild to moderate disability resultant from MS are available (Kim et al., 2019; Latimer-Cheung, Pilutti, et al., 2013).

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Yet, the evidence from exercise activity in MS RCTs does not translate to real-world activity increases. People living with MS are typically less active than the general population (Kinnett-Hopkins et al., 2017), and around one-quarter of persons with MS may not do any physical activity at all (Learmonth et al., 2022). Two decades of RCTs have indicated the multitude of benefits of exercise in MS, such as improvement in strength, physical fitness, walking performance, fatigue, balance, and quality of life (Motl & Pilutti, 2012; Motl et al., 2017). However, there is a need to identify why the research is not translating to real-world participation.

The concern of research findings not translating into real-world changes is being investigated from several perspectives (Rapport et al., 2018, 2021). In exercise and MS, one proposal is to include behaviour change theory in the design of exercise programs and exercise promotion (Motl, Pekmezi, & Wingo, 2018; Riemann-Lorenz et al., 2021). Another proposal identifies consumer barriers to exercise participation including environmental and personal barriers (Learmonth & Motl, 2016). Lastly, a recommendation on educating healthcare providers in the ongoing promotion of exercise in MS is being developed (Motl, Barstow, et al., 2018). However, one area lacking focus is the systematic study of research methodology that underpins exercise research in MS. This study must be undertaken as a priority to address the lack of MS exercise research translating into real-world participation (Riemann-Lorenz et al., 2021).

Implementation science is “*the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care*” (Eccles & Mittman, 2006). We must consider the work of implementation science when considering the feasibility of MS exercise research. Building on implementation theories, models, frameworks and evaluation will allow refinement in the execution of research through implementation strategies to support and improve uptake of exercise and optimise their impact for people living with MS (Hallingberg et al., 2018). Our study lays the foundation for research on how feasibility from an implementation science lens can play an important role in addressing the *valley of death*, the phase between research and successful innovation (Hudson & Khazragui, 2013), and ensuring later implementation trials can be more translatable by acknowledging potential bottlenecks at the feasibility phase and before real-world environment research.

Feasibility plays an essential role in improving the conduct and quality of a RCT (Learmonth & Motl, 2018). Feasibility within the implementation science literature was initially conceptualised more than a decade ago as an important implementation outcome (Proctor et al., 2011). In this pivotal work, feasibility was highlighted as how a new treatment, innovation, or intervention can be successfully used or carried out (Proctor et al., 2011). Although, Proctor et al.’s (2011) framework has since been widely applied within the implementation science community, there is still a shortage of

feasibility indicators within the implementation science literature (Pearson et al., 2020). In addition, there is a need to combine Proctor et al.’s (2011) framework of feasibility as an implementation outcome and position it within the broader feasibility literature (Hallingberg et al., 2018; Learmonth & Motl, 2018; Teresi et al., 2022).

A paradigm shift within implementation science happened with the introduction of a simultaneous assessment of effectiveness and implementation, described as Hybrid effectiveness-implementation trials. Hybrid effectiveness-implementation trials (Type 1, 2, 3) are used to distinguish between implementation and clinical trials (Curran et al., 2012; Lane-Fall et al., 2019). Hybrid effectiveness-implementation trials outlined in the literature have focused on real-world environment research which has shown effectiveness or at least very strong efficacy (Curran et al., 2012; Lane-Fall et al., 2019) and incorporate questions about implementation simultaneously into studies of effectiveness (i.e., Type 1) or simultaneously test the impact of one or more implementation strategies alongside the effectiveness of one or more interventions (i.e., Type 2) (Proctor et al., 2022).

Embedding feasibility and pilot studies within Type 1 and Type 2 effectiveness-implementation trials are worthy of attention. However, despite the methodological advances of hybrid designs this does not resolve the fact that the effects of implementation strategies have only ever been modest (Lewis et al., 2018; McIntyre et al., 2020; Pearson et al., 2020; Powell et al., 2011; Powell et al., 2015). To improve the effectiveness of implementation strategies and improve the uptake of exercise in real-world participation, we turn to the broader feasibility literature (process, resource, and management) together with implementation science for answers.

There are ample reasons to why feasibility and implementation science should meet in exercise and MS. For example, feasibility when considered at the pre-efficacy phase is a critical step in assessing the **value** to progress to an effectiveness study of exercise in an MS population (Learmonth & Motl, 2018). Feasibility research highlights an opportunity within implementation science to efficiently narrow research-to-practice gaps and provide more finely tuned guidance early on for implementation strategies and intervention optimisation. To remedy the need to narrow the research-to-practice gap, we propose that just as implementation science frameworks can evolve (Damschroder et al., 2022; Smith J., 2022), implementation science must too (Rapport et al., 2022) through a keen focus on feasibility (Smith, Braithwaite, O’Brien, Smith, Tyrrell, et al., 2022; Smith, Braithwaite, O’Brien, Smith, Tyrrell, et al., 2022). This alternative view contrasts the existing belief that implementation science is exclusive to strong efficacious work or real world efficacy as per Hybrid effectiveness-implementation trials (Lane-Fall et al., 2019). Instead, we propose in addition to this, implementation science also has its place in early feasibility research to improve implementation strategies for efficacy and effectiveness phases. Our aim in this study was therefore to broaden the implementation science

**Table 1.** Glossary of key terms and definitions.

| Terms  | Acronym | Definition   |
|--|---------|--|
| Acceptability  |         | Acceptance of the intervention ( <a href="#">Learmonth &amp; Motl, 2018</a> )  |
| Changing behaviour towards aerobic and strength exercise in MS | BASE    | Case study example.<br>BASE is a feasibility study that explore the delivery of a remotely supervised, guidelines-based exercise programme for persons with multiple sclerosis ( <a href="#">Learmonth et al., 2021</a> )  |
| Efficacy   |         | Determine whether an intervention produces the expected result under ideal circumstances ( <a href="#">Gartlehner et al., 2006</a> )   |
| Effectiveness  |         | Measure the degree of beneficial effect under “real world” clinical settings ( <a href="#">Gartlehner et al., 2006</a> )   |
| Feasibility  |         | A feasibility study asks whether something can be done by asking about the resource needs, how accepted the intervention is by those delivering and receiving the intervention and finally asks; should we proceed with it? ( <a href="#">Learmonth &amp; Motl, 2018</a> )   |
| Consolidated framework for implementation research             | CFIR    | An implementation science framework is used to help with intervention design and contextual factors to recognise how multiple levels of behaviour change, operate, and influence implementation  |
| Guidelines for exercise in MS                                  | GEMS    | Case study example<br>The GEMS examines the feasibility of a home-based exercise training program based on recent physical activity guidelines and principles of behaviour change for improving symptoms and health-related quality of life (HRQOL) in adults with multiple sclerosis (MS) ( <a href="#">Learmonth et al., 2017</a> )  |
| Hybrid effectiveness-implementation trials                     |         | Promote examination of effectiveness and implementation outcomes within a study ( <a href="#">Curran, 2020</a> ; <a href="#">Lane-Fall et al., 2019</a> )  |
| Implementation research  |         | Implementation research looks at how best to do the ‘thing’ (intervention) ( <a href="#">Curran, 2020</a> )  |
| Implementation strategy  |         | The ‘stuff’ (e.g., training, reminders, audit, and feedback) we do to support the ‘thing’ intervention ( <a href="#">Curran, 2020</a> )  |
| Implementation science   |         | Implementation science is defined as the scientific study of methods to promote the uptake of research findings and other evidence-based practices into routine practice ( <a href="#">Eccles &amp; Mittman, 2006</a> )  |
| Intervention   |         | The intervention is the ‘thing’ e.g., programs, practices, principles, procedures, products, pills, and policies ( <a href="#">Curran, 2020</a> )  |
| Medical research council                                       | MRC     | Guidelines for designing and evaluating feasibility pilot studies (medical research council)   |
| Motor improvement in neurological conditions in MS             | MINC-MS | Case study example.<br>MINC-MS is a 12-week exercise intervention using a neuro-animation intervention designed to make therapy more engaging and motivating. In this study, an infrared camera tracks participants’ arm movements which control a virtual dolphin on a screen. The aim is to catch fish and stay away from predators. People with mild to moderate MS train twice per week for 1 hour time on task. The primary aim of this feasibility study is to determine the feasibility of conducting a multi-center definite randomized control trial (RCT). ( <a href="#">van der groen et al., unpublished</a> ) |
| Multiple sclerosis   | MS      | Multiple sclerosis (MS) a chronic, progressive disease of the central nervous system. is among the most common non-traumatic disabling diseases to affect young adults ( <a href="#">Kobelt et al., 2017</a> )   |
| Phases of trials of complex interventions                      |         | Phase 0 - basic science (i.e., the development of behavioural, cognitive, affective or social neuroscience), to testing the feasibility of delivering intervention and acceptability to providers and patients (if and how an intervention can be done, phase I pilot/feasibility studies), to comparing the intervention to an appropriate alternative (phase II/III; efficacy) and, lastly, testing whether an intervention works in everyday practice and gains are maintained in the long term (phase IV effectiveness, or phase V translation) ( <a href="#">Learmonth &amp; Motl, 2018</a> )                         |
| Traditional research pipeline                                  |         | Test on a small scale–replicate–expand to a large scale ( <a href="#">Hill &amp; Knox, 2022</a> )  |

remit and shine a light on its applicability to feasibility using exercise case examples in MS. By mapping and proposing a new model and showcasing where feasibility meets implementation science using a flexible unobtrusive qualitative document analysis methodology (See [Table 1](#) for key terms and definitions).

## Methods

Ethics approval and consent to participate was not applicable to our study. Conducting a document analysis has been documented to eliminate some of the ethical concerns associated with other qualitative methods ([Morgan, 2022](#)). For example, document analysis is a form of qualitative research whereby the researchers understand the actual documents to give voice and meaning through the analysis of the documents ([Bathmanathan et al., 2018](#)). Document analysis can include peer-reviewed, grey literature or a combination of both, as such, sourcing and selecting documents used for systematic evaluation in our particular study are presented in the form of peer-reviewed published or unpublished documents ([Adamson et al., 2016](#); [Learmonth et al., 2017](#); [Learmonth et al., 2021](#); van der Groen, Learmonth, van Rijn, Smith, and Edwards, Unpublished). The analytic procedure entails appraising, and synthesising data contained in documents by coding text into themes and subthemes ([Bathmanathan et al., 2018](#)). Our study also adheres to the consolidated criteria for reporting qualitative research (COREQ) ([Tong et al., 2007](#)) reporting guidelines.

### Document Sources

The following document sources were selected by our group to answer our research question on where feasibility meets implementation science: (a) three protocol papers: BASE ([Learmonth et al., 2021](#)), GEMS ([Adamson et al., 2016](#)), and the MINC-MS trial (van der Groen et al., Unpublished, for more details, see [Table 2](#)); (b) one results paper: GEMS ([Learmonth et al., 2017](#)). These standalone document sources (See [Table 2](#)) were selected based on purposive sampling with documents that incorporated exercise prescription elements and behaviour change, which is suggested as optimal delivery ([Motl, Pekmezi, & Wingo, 2018](#)). Most importantly, these document sources were feasibility studies that incorporated aspects of implementation science, and could track change and development ([Bathmanathan et al., 2018](#)), but also provide different examples of MS exercise interventions allowing for analogies to be made between them. As with multiple-case analysis approaches ([Churruca et al., 2019](#)), some of the researchers involved in the different case examples are authors of our paper, so the cases we selected have either been published or presented elsewhere and this helped in ensuring authenticity, credibility, representativeness and meaning of documents ([Morgan, 2022](#)).

## Analysis

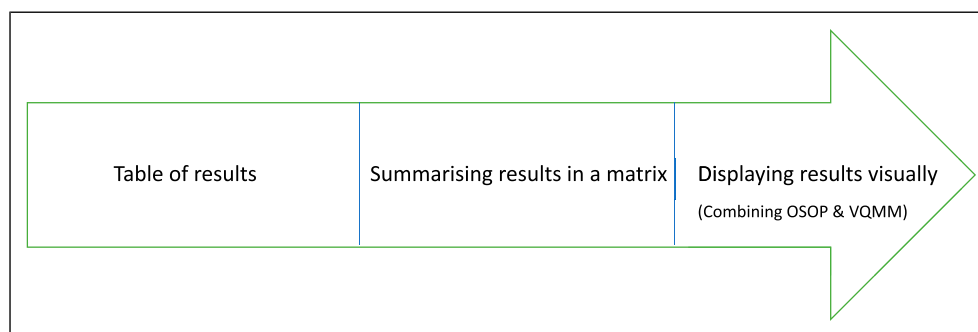
The case examples we draw upon are considered together by using document analysis methodology combined with other methods such as the One Sheet of Paper (OSOP) method ([Ziebland & McPherson, 2006](#)) that summarises data. In addition, we present a simplified account of the data through a visual qualitative mapping method (VQMM) ([Smith, Lee, Ellis, Ijaz, & Yin, 2021](#)) to facilitate an understanding of our qualitative results (See [Figure 1](#)). This process was supported by NVivo 12 Plus ([QSR, 2019](#)).

We used the [O’Cathain et al. \(2015\)](#) and the MRC (Medical Research Council) guidelines to identify in advance some coding based on exploratory trials (feasibility studies) ([Bonell et al., 2011](#); [Craig et al., 2008](#); [Medical Research Council, 2000](#); [Moore et al., 2015](#)) where the complete evaluation is to be an RCT ([Medical Research Council; O’Cathain et al., 2015](#)). The a-priori themes include ‘intervention design’, ‘delivery refinement’, ‘acceptability’, and ‘modifications’ (Medical Research Council). This example of a priori themes is a deductive coding process within template analysis ([Brooks & King, 2014](#)). We took great care throughout to ensure that our ongoing analysis was not blinkered or unduly constrained by our initial template design ([Brooks & King, 2014](#)). To further reduce the possibility of any blinkering effect, the selection of a-priori themes only occurred after careful consideration and refining of our coding process (JS, an experienced male qualitative researcher discussed ongoing coding developments with the wider team) ([Hull et al., 2019](#); [Rolland et al., 2021](#)). For example, a-priori codes were either merged (intervention design, delivery refinement, optimisation, and modifications became ‘*Optimise and adapt intervention design*’) or codes that did not fit the pre-determined coding framework were given a new code (‘*use of theory, models and frameworks*’, ‘*identify those people delivering the intervention in the research trial/efficacy effectiveness stage*’) (See [Table 3](#)). Alternatively other a-priori codes (acceptability) were merged into new codes (acceptability was merged into ‘*Evaluate multiple aspects of feasibility*’). There was no attempt to capture data saturation in line with other research based on reflexive thematic analysis ([Braun & Clarke, 2021](#)), recognising our contribution is interpretative, and meaning is generated through the interpretation of data ([Smith, Braithwaite, O’Brien, Smith, Tyrrell, et al., 2022](#); [Smith, Braithwaite, O’Brien, Smith, Tyrrell, et al., 2022](#)).

## Results

### Five Themes

Template analysis ([Brooks & King, 2014](#)), was used with five themes iteratively developed (See [Table 3](#)), based on four document sources. [Table 4](#), summarises the themes and sub-



**Figure 1.** Displaying the data

**Table 2.** Case Study research on a range of feasibility studies critically examined.

| Case Examples  | Feasibility Studies   |  |   |
|--|---|--|---|
|  | Intervention  | Description  | Outcomes  |
| <b>BASE</b> (Learmonth et al., 2021)                       | Changing behavior towards aerobic and strength exercise                   | Phase I study<br>Remotely delivered<br>A 16-week progressive exercise program to achieve clinical exercise guidelines (Kim et al., 2019; Latimer-Cheung, Martin Ginis, et al., 2013)<br>Progressing to a minimum of two sessions of 30 minutes of moderate-intensity aerobic walking and two sessions of home-based resistance exercise sessions<br>Supported by social cognitive theory of behaviour change principles via six coaching calls and six educational newsletters | Primary outcome: Exercise participation<br>Secondary outcome: Symptoms, and correlates of behaviour change at baseline, month four, month five and month 11   |
| <b>GEMS</b> (Adamson et al., 2016; Learmonth et al., 2017) | Guidelines for exercise in MS   | Phase I study. Remotely delivered. A 16-week progressive exercise program to achieve clinical exercise guidelines (Latimer-Cheung, Martin Ginis, et al., 2013). Progressing to two sessions of 30 minutes moderate-intensity aerobic walking and two sessions of home-based resistance exercise sessions. Supported by social cognitive theory of behaviour change (Bandura, 2004) principles via six coaching calls and six educational newsletters                           | Primary outcome: Exercise participation,<br>Secondary outcome: Symptoms, and correlates of behaviour change at baseline, month four, month five and month 11  |
| <b>MINC-MS</b> (van der groen et al., unpublished)         | Motor improvement in neurological conditions (MINC) in multiple sclerosis | Phase I study. MS in-clinic delivery 12-weeks of MindPod training (2 × 60 minutes per week) involving exergame rehabilitation  | Primary outcome: Feasibility. Secondary outcome – Upper limb function.<br>Tertiary outcome – cognition, fatigue, quality of life, biological. Tertiary outcome – Does the intervention change exercise behavior long-term |

themes with our document analysis methodology following a visual account (shown in Table 5) of the data combining the OSOP and VQMM methods (See Table 4) (Smith et al., 2021). Therefore, highlighting that document analysis can be used in

different ways that other qualitative approaches may not be able to, and for assisting in identifying gaps (See Figure 1).

Our evidence from the document sources demonstrates how some aspects of implementation science are already being

Table 3. Table of Results.

| Document Source                                       | Theme 1: Use of Theory, Models and Frameworks  | Theme 2: Evaluate Multiple Aspects of Feasibility  | Theme 3: Optimise and Adapt Intervention Design  | Theme 4: Specify the Implementation Strategy   | Theme 5: Identify Those People Delivering the Intervention in the Research Trial/Efficacy Effectiveness Stages  |
|---|--|--|--|--|---|
| <b>MINC-MS. Protocol</b> (van der Groen et al., 2022) |  | <b>Process/management/scientific:</b><br>"Based on process, resource, management, and scientific metrics for feasibility." "This study will gather outcomes based on process, resource, management and scientific metrics for feasibility." <b>Acceptability:</b> "The acceptability of this intervention by participants and staff delivering the intervention." "Findings from this study will establish whether a full RCT is feasible and will inform sample size and outcome measures of a definite trial. The findings of this feasibility study will be generalisable to a similar recruitment setting."  | <b>Evaluation:</b> "The Rapid Health Implementation Proforma's (RHIP) is a rapid qualitative data collection tool used in exergames taking the form of an open-ended, text-box survey, comprising a brief number of questions. RHIP allows participants to expand on survey responses and diversify, to an extent, from the topic area."   |  | <b>Staff/primary therapist:</b><br>"Staff delivering the intervention/Clients primary therapist."   |
| <b>BASE Protocol</b> (Learnmonth et al., 2021)        | <b>Social cognitive theory.</b> "The behavioural principles will be based on SCT (Social Cognitive Theory)." <b>COM-B (capability, opportunity and motivation).</b> "Understanding adherence using behaviour change models (i.e. Capability, Opportunity and Motivation); and exercise programme preferences". <b>Self-Determination theory:</b> "Identifying difference in motivation between active and less active persons with MS, supported the post hoc addition of outcomes of Self-Determination Theory." <b>TPB (theory of planned behaviour):</b> "Identifying difference in motivation between active and less active persons with MS, supported the post hoc addition of outcomes of Self-Determination Theory and Theory of Planned Behaviour." | <b>Process/management/scientific:</b><br>"We will gather data on process, resource, management and scientific feasibility." "Process Feasibility will be measured via: 1. Recruitment rate (number of interested and eligible participants/number of persons viewing recruitment site) and 2. Reaction to both randomisation stages (based on reasons for drop-out after the announcement of group allocation). Resource feasibility will be measured via 3. Retention rate (reported via a CONSORT diagram [26], 4. Reported barriers to participation, 5. Adherence with the protocol (total sessions completed/prescribed sessions (i.e., 2 aerobic, 2 resistance sessions per week), 6. Compliance with the protocol (e.g., total completed exercises (set x reps x exercise)/prescribed exercises (set x reps x exercise), 7. Participants reaction to the survey for outcome measures (response to question on length of study), 8. Access to and cost of equipment, and staff time requirements (total hours/participant), 9. Hours of staff training, and 10. Participant and coaches evaluation of the programme. Management will be measured via: 11. Access to/delivery of equipment, 12. The number of data collection prompts required (number of emails/telephone calls required as survey reminders to participants). Scientific feasibility will be measured via the scientific outcomes." | <b>Evaluation:</b> "To take a realist evaluative approach to determine how the intervention works, we will gather feedback from both participants and coaches." <b>Consumer and coach feedback optimising the intervention:</b> "We further engaged with consumers prior to beginning the study, and important concerns were raised around the impact of public health events affecting Australians at the beginning of the project (namely the aftermath of the Australian Bushfires and the beginning of the COVID19 pandemic). Additions made at this time following consultation with consumers, were 1. an increase in participant recruitment, as a response to the closure of many exercise-based health services; 2. adjustment to the exercises delivered in the first 2 weeks of the programme to reduce the definite reliance on equipment, as a response to delays in purchasing home-exercise equipment and delays in postal services delivering equipment to participants; 3. the addition of survey questions." | <b>Implementation Strategy:</b><br>"The participants in the exercise condition will all receive the BASE package of manual, individualised exercises accessed via an online library of exercises, reminder text messages, behavioural coaching video calls, behavioural newsletters to encourage exercise adherence, mini-pedometers, and resistance bands." | <b>Coaches:</b> "Coaches will be physiotherapists, exercise physiologists or student exercise physiologists. BASE participants will be partnered with the same coach for the duration of the first 4 months of the intervention. These behavioural coaches will receive manualised training on the BASE." |

(continued)

Table 3. (continued)

| Document Source                             | Theme 1: Use of Theory, Models and Frameworks  | Theme 2: Evaluate Multiple Aspects of Feasibility  | Theme 3: Optimise and Adapt Intervention Design   | Theme 4: Specify the Implementation Strategy   | Theme 5: Identify Those People Delivering the Intervention in the Research Trial/Efficacy Effectiveness Stages |
|---|--|--|---|--|--|
| <b>GEMS Protocol</b> (Adamson et al., 2016) | <b>SCT (social cognitive theory):</b> "Approaches based on social-cognitive theory (SCT) can maximize adherence of homebased physical activity programs. SCT indicates that self-efficacy, outcome expectations, facilitators, and strategies are important determinants of physical activity in MS and could be integrated into home-based programs for changing behavior." | <b>Process/management/scientific:</b> "This study will gather outcomes based on process, resource, management and scientific metrics of feasibility. These metrics are summarized." "This study will gather outcomes based on process, resource, management and scientific metrics of feasibility. These metrics are summarized." "The feasibility study design will allow for the research team to gather vital information on the process, resource, management and scientific feasibility of our approach." | <b>Tailoring the intervention design:</b> "In the event that a person cannot achieve the volume, we will instruct them to do the following. First, we will encourage them to slow down to a pace that they feel comfortable at for 10 min of walking. If this does not result in the individual being able to meet the time requirement for the walking, we will secondly advise them to walk as long as they can, take a 2-3 min break and then resume until the time is complete." "Furthermore, the instructions for the resistance training exercises include adaptations if they are too difficult and participants will be encouraged to use those adaptations if they cannot complete the resistance training as prescribed." "Lastly, if participants miss fewer than 2 weeks of exercise sessions in a row, they will be instructed to continue with the progression as usual (if adaptations are needed they will discuss this with their exercise coach). If the participant misses 2 or more weeks of exercise sessions in a row, the exercise coach and participant will discuss an appropriate time to recommence." "There may be individuals who cannot achieve the prescribed exercise volume in the beginning of the program. Discovering if this is the case is an important part of this feasibility trial." <b>Evaluation:</b> "Feedback will take a successive two-pronged approach, (a) completion of a mail-delivered survey containing questions for evaluation of the program and its materials and (b) completion of a telephone interview for further evaluation of the program and its materials as well as participant experiences. The telephone interview will be undertaken by a researcher experienced in qualitative interviews. Interviewers will not conduct interviews with participants whom they coached during the intervention. These interviews will contain questions about participants' expectations of the program, perceptions of the process of becoming enrolled in the program, actual experiences in the program (including any perceived benefits and problems experienced), and perceptions of the interactions with the research staff, materials, as well as the burden experienced from the home-based assessments (i.e. wearing the accelerometer and completing the large number of questionnaires)." <b>Optimising and adapting intervention design</b> "The feasibility data gathered in the GEMS program will guide future efforts in this area by determining optimal recruitment strategies, integrity of the study protocol, appropriateness of outcome assessments, and considerations for methodology alterations. This is essential for subsequent research on non-supervised exercise in MS." | <b>Implementation strategy:</b> "A review of the correlates of physical activity behaviour indicates that targeting components of SCT in individuals with MS is an effective way of increasing physical activity behaviour, whereas other theories of health behaviour change lack principles for targeting behaviour change and simply provide predictive information of behaviour engagement [21]. We have provided evidence that such interventions can be delivered through newsletters supplemented with one-on-one online video chats with a behavioural coach in persons with MS." "Program integrates principles of SCT through newsletters and online video-chats for promoting and maintaining behaviour change." "The newsletters provide instructional material on each of the aforementioned topics, websites to visit for more information, testimonials of individuals who have experienced benefits of exercise, and tips for participants to try at home." "One-on-one, semi-structured, online video-chat sessions with MS-exercise specialists will be conducted using web cameras and Skype, or other similar programs (e.g. Facetime) based on participant resources and preferences. If participants do not have access to the Internet or Skype, the online video-chats will be replaced with phone calls." "The online video-chats will be designed to provide participants with feedback and information on how to progress through the exercise program as well as to provide supportive accountability, this term refers to accountability to a coach who is seen as trustworthy, benevolent, and having expertise for the purpose of increasing adherence to the intervention." <b>BCT's (behaviour change techniques):</b> "Outcome expectations, self-monitoring, goal-setting, self-efficacy, barriers and facilitators." |  |

(continued)



Table 3. (continued)

| Document Source                               | Theme 1: Use of Theory, Models and Frameworks  | Theme 2: Evaluate Multiple Aspects of Feasibility  | Theme 3: Optimise and Adapt Intervention Design   | Theme 4: Specify the Implementation Strategy  | Theme 5: Identify Those People Delivering the Intervention in the Research Trial/Efficacy Effectiveness Stages |
|---|--|--|---|---|--|
| <b>GEMS Results:</b> (Learmonth et al., 2017) | <b>SCT (social cognitive theory):</b> "Research including principles of behavioural change based on Social Cognitive Theory (SCT) in persons with MS." | <b>Process/management/scientific</b> "Feasibility was assessed in the domains of process (e.g., recruitment), resource (e.g., monetary costs), management (e.g., personnel time requirements) and scientific outcomes (e.g., treatment effect)." "We gathered data based on the feasibility metrics of process, re- source, management and scientific outcomes. These metrics, monitoring and assessment strategy, data source and outcome variable computation method." <b>Acceptability:</b> "The results support the feasibility and acceptability of a home-based exercise intervention based on physical activity guidelines and supplemented with behavioural strategies for adults with mild-to-moderate MS." "Our retention rate (89%) was comparable with past research, suggesting overall study acceptability." "Qualitative feedback indicated a high level of acceptability of the research." | <b>Consumer and coach feedback optimising the intervention design:</b> "We further developed our intervention using a "person based approach", by gathering informal feedback regarding our manual and equipment from 4 persons with MS. We received positive and constructive feedback from these persons and this feedback resulted in changes within the program manual (e.g., instructions on programme progression and completion of the log-book)." | <b>Implementation strategy:</b> "We further provided 6 newsletters based on SCT which were delivered in a titrated fashion (i.e., weeks 2, 4, 6, 9, 12 and 15), and these were delivered through email and USPS. On the same schedule, participants engaged in one-on-one Skype sessions with a behavioural coach for discussing the newsletter content as well as progress with the exercise program." "Behavioural change interaction Video-chats Newsletter. Behavioural change session content Week 1 introduction to programme. Designed to provide participants with feedback and information on how to progress through the exercise program as well as to provide social accountability. Newsletters provide instructional material on specific behavioural change content, websites to visit for more information, testimonials of individuals who have experienced benefits of exercise, and tips for participants to try at home." <b>BCT's (behaviour change techniques:</b> "Self-monitoring, Goal-setting, Self-efficacy, Overcoming Barriers, Identifying facilitators." |  |

Table 4. Summarising results by using a matrix to show how an implementation science lens can complement feasibility studies based on MS document sources.

|                   | Themes  |  |  |  |  |
|-------------------|---|--|--|--|--|
|                   | Theme 1: Use of Theory, Models, and Frameworks  | Theme 2: Evaluate Multiple Aspects of Feasibility                    | Theme 3: Optimise and Adapt Intervention Design          | Theme 4: Specify the Implementation Strategy | Theme 5: Identify Those People Delivering the Intervention in the Research Trial/Efficacy Effectiveness Stages |
| <b>Sub-themes</b> | Self-determination  | Process, resource, management and scientific metrics for feasibility | Consumer and coach optimisation of intervention design   | Behaviour change techniques (BCT's)          | Staff/primary therapist  |
|                   | Theory of planned behaviour   | Acceptability  | Optimising the intervention design                       | Implementation strategy                      | Coaches/physiotherapists/ exercise physiologists/ student exercise physiologists                               |
|                   | Social cognitive theory (SCT) in persons with MS. COM-B (capability, opportunity, and motivation) |  | Adapting/tailoring the intervention design<br>Evaluation |  |  |

**Table 5.** Visually displaying results combining the OSOP and VQMM.

| Document Source  | Use of Theory, Models, and Frameworks | Evaluate Multiple Aspects of Feasibility | Optimise and Adapt Intervention Design | Specify the Implementation Strategy | Identify Those People Delivering the Intervention in the Research Trial/ Efficacy Effectiveness Stages |
|------------------|---------------------------------------|--|--|-------------------------------------|--|
| GEMS Protocol    | ✓                                     | ✓  | ✓                                      | ✓                                   | x  |
| GEMS Results     | ✓                                     | ✓  | ✓                                      | ✓                                   | x  |
| BASE Protocol    | ✓                                     | ✓  | ✓                                      | ✓                                   | ✓  |
| MINC-MS Protocol | x                                     | ✓  | ✓                                      | x                                   | ✓  |

Key.

X = Implementation science gaps.

✓ = Implementation science aspects identified.

integrated much earlier at the feasibility phase in MS (Phase I) research, rather than implementation science assumed to only start at phases of strong efficacy or effectiveness (e.g., Phase II/III testing). By using implementation science at the feasibility phase (Phase I), some barriers are pre-identified, anticipated, and understood before subsequent strong efficacy (Phase II/III), and effectiveness research (Phase IV). Such practice could improve the on-going fit and quality of implementation strategies, an important finding based on real-world case study examples in MS and exercise that are yet to establish strong efficacy or effectiveness (Adamson et al., 2016; Learmonth et al., 2017; Learmonth et al., 2021; van der Groen et al., Unpublished).

## Discussion

We document case examples to map and develop the idea of a cyclical model (Hill & Knox, 2022; Knox et al., 2018) providing real-world needs outlined by our document sources, highlighting where feasibility meets implementation science. We herald that in health conditions such as MS, the benefits of participation in exercise are vital for symptom management, and may offer much benefit to the disease progression, yet exercise participation is still low within this population (Marck et al., 2020). Our proposed cyclical model of feasibility and implementation science outlined below may offer an important sea change. Our findings, therefore, present a critical step in preliminary testing of the intervention design, delivery, and implementation strategies and methods. There are five clear themes that have been visually represented as an alternative qualitative approach that offer actionable guidance to future studies (Pfaff & Schmitt, 2021). Via case examples of exercise research in MS, we have shown a comprehensive picture of the interaction between testing clinical feasibility and adopting principles of implementation science that can be harnessed together when testing research for clinical practice.

### *Theme 1: Include the use of Theory, Models, and Frameworks*

Theory is often underused, however, determinant frameworks, classic theories, implementation theories, and evaluation can all help to guide implementation practice (Birken et al., 2017; May, 2013). Theories therefore, describe aspects that might be important to evaluate (May, 2013; Nilsen, 2015). This is because a good theory explains how and why specific relationships lead to particular events and therefore how the implementation strategies are thought to work and sustain interventions (Albers et al., 2020; Rapport et al., 2022). Across the case studies, of BASE and GEMS a mixture of different classic behavioural theories were being considered and tested, such as the use of Self-Determination Theory, Theory of Planned Behaviour (individuals attitude, subjective norms, and perceived behavioural control) and Social Cognitive Theory (reciprocal determinism, behavioural capability, expectations, observational learning, reinforcements, and self-efficacy – seen as the most personal factor in changing behaviour) were used (Adamson et al., 2016; Learmonth et al., 2017; Learmonth et al., 2021). Other examples of behavioural theories can be seen in BASE with the COM-B, (capability and/or opportunity and motivation - as three key factors capable of changing behaviour) (Learmonth et al., 2021) that can help explain behaviour change in adopting exercise behaviour for those persons living with MS as they can target correlates of physical activity behaviour and consider the demands of living with MS. Further, in the BASE document source (Learmonth et al., 2021) the importance of including a realist theory approach (Brockschmidt & Wadey, 2022) to programme implementation (a theory that explains how and why particular types of interventions work to generate the outcome/s of interest) was indicated. This can help explain “how the intervention works”, “why does the intervention work”, how strategies bring about intended or unintended results,

“for whom does it work” and “in what circumstances does it work” (Pawson et al., 2005).

### *Theme 2: Evaluate multiple aspects of feasibility*

Multiple feasibility aspects from our case examples relate to process, resource, management and scientific outcomes (Adamson et al., 2016; Learmonth et al., 2017; Learmonth et al., 2021; van der Groen et al., Unpublished). These feasibility metrics are invaluable to Phase II or Phase III (Campbell et al., 2000; Friedman et al., 2015). For example, resource feasibility measures the training need and competence of personnel delivering the intervention. Poor training or low competence of personnel may impact the results of the intervention (Chen et al., 2022; Tickle-Degnen, 2013). Further, management feasibility addresses staff time commitments, providing vital information for policy-makers when weighing up which interventions to consider for future research relevant for clinical practice, and this information could further contribute to understanding intervention fidelity (Smith, Braithwaite, O'Brien, Smith, Tyrell, et al., 2022). There is urgency needed in establishing the goals of preliminary studies as research funding applications are assessed based on a varied list of standards which may lack consistency. In addition, the people intended to deliver and receive the intervention need to accept that intervention, if there is low acceptability, it could have an overall effect on the intervention (Smith, Braithwaite, O'Brien, Smith, Tyrell, et al., 2022). Acceptability is, therefore, an important aspect of feasibility (Learmonth et al., 2017; van der Groen et al., Unpublished), and if acceptability is ignored at the Feasibility phase (Learmonth & Motl, 2018), we miss a variety of opportunities to inform later phases of efficacy and effectiveness (Smith et al., 2022).

Individual concepts such as feasibility and acceptability are therefore necessary but insufficient on their own (Klaic et al., 2022). Our findings align with the guidelines that state we must assess multiple aspects of feasibility such as acceptability, intervention design, delivery refinement, optimisation, and modifications before full-scale evaluation (Craig et al., 2008; Teresi et al., 2022). MRC guidelines in 2008 (Craig et al., 2008) and other studies (Learmonth & Motl, 2018) also advocate for this cyclical approach whereby movement between piloting/feasibility and intervention development may sometimes be needed when changes to intervention design may be necessary (Hill & Knox, 2022). The idea of assessing multiple aspects of feasibility (Bowen et al., 2009; Craig et al., 2008; Medical Research Council), has recently been updated and advocated within the latest guidelines (Teresi et al., 2022).

### *Theme 3: Optimise and adapt the intervention design*

Involving consumer and coach feedback, optimising and tailoring the intervention design, and evaluation were subthemes presented to describe the overall theme, which

is to optimise and adapt the intervention design. Such a guideline-driven approach to consumer review is critical to understand clinical uptake of our exercise interventions. The intervention design and the fit of the intervention into settings should be considered at the feasibility phase (Craig et al., 2008). This is in line with the MRC guidelines for a full evaluation, where the evaluation is an RCT (Medical Research Council; O'Cathain et al., 2015) together with more recent guidelines advocating, as already discussed, for assessing multiple aspects of feasibility (Teresi et al., 2022), suggesting implementation science can play a central role. We should question why studies would design interventions that ultimately do not fit the context to which they will need to be applied (Chambers et al., 2013; Smith et al., 2020), and ask does implementation science hold the promise of unpacking the link between context and outcomes (Rees et al., 2022) as highlighted with the use of a realist approach in the feasibility study of BASE (Learmonth et al., 2021). Therefore, adaption and tailoring to context should be considered early and in terms of how we ensure that the intervention will fit the context of its intended setting, group, or population. The opportunity therefore lies in designing the best possible intervention at the start (feasibility Phase 1). Doing so will help later phases, by identifying early on the determinants of current behaviour and desired behaviour change which can help in the selection of the components of the implementation strategies that can target key determinants, therefore, minimise the risk of replicating these barriers when scaling the intervention across sites or scaling across healthcare systems. Implementation Science Frameworks such as the Consolidated Framework For Implementation Research (CFIR) are useful, because this framework considers how an intervention is designed will affect how well it can be implemented (Damschroder et al., 2009). On author reflection, our study highlights something missing within our case examples that included more thought over intervention design considerations using implementation science frameworks to guide intervention design optimisation, and therefore this too needs to be employed in feasibility studies (Chambers et al., 2013). In addition, the intervention characteristics of the CFIR (i.e., intervention source complexity, adaptability, relative advantage, trialability) will inherently complement the feasibility phase of intervention design (Landes et al., 2019) because, by the time you reach past this stage, it potentially is too difficult, or too late (fixed in effectiveness research) to change, adapt or optimise a working intervention. For feasibility, identifying enablers to achieve on-going optimal trial design is a worthwhile goal (Smith, Braithwaite, O'Brien, Smith, Tyrell, et al., 2022). Rich information on barriers and facilitators to research implementation can be used to modify the trial before testing efficacy and effectiveness and this can also become an iterative process. Collecting

such data at the outset of our research goals allows us to implement the principles of behaviour change into our scientific research pursuits. Therefore, we are armed with knowledge about contextual fit, and the barriers and facilitators at the early feasibility phase and can be proactive rather than reactive later down the line (as in efficacy and effectiveness studies) (Chambers et al., 2013).

#### ***Theme 4: Specify the Implementation Strategies Within the Feasibility Study***

Implementation strategies are defined as “methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice” (Curran et al., 2012; Proctor et al., 2013, p. Pp. 140). Despite the rapid rise of implementation science as a discipline (Sales et al., 2019), the quality of implementation trials has been criticised and the effects of implementation strategies on implementation have only been modest (Grimshaw et al., 2004; Lewis et al., 2018; Powell et al., 2015). The reasons for this have seldomly been reported and are poorly understood (McIntyre et al., 2020). Herein we present the view that designing implementation strategies can be optimised within feasibility studies in *preparation* for an RCT. The feasibility phase is a missed opportunity not to align implementation strategies with implementation outcomes (e.g., feasibility and acceptability) and work towards early optimisation of the intervention (Rudd et al., 2020). The implementation strategies in the MS context based on our document sources are the strategies (reminders, education etc.) used to support the uptake of the exercise intervention (Curran, 2020; Smith et al., 2022). To effectively engage in implementation science research, it is a pre-requisite to understand the role of behaviour change in developing an implementation strategy (Handley et al., 2016). Our document sources provide clear evidence that implementation strategies for studies that have yet to establish efficacy or effectiveness hold the key to early optimisation generating useful knowledge that can be used across the translational process for the utility and application of implementation strategies to support the intervention (McHugh et al., 2018). Theme 1 (theory) and Theme 4 (implementation strategy) are interlinked. This is because the use of theory such as Social Cognitive Theory (SCT), and Behaviour Change Techniques (BCT's) used in the document sources structure understanding of barriers and can help to develop implementation strategies in this pre-efficacy phase, providing an emerging approach at the intersection of feasibility and implementation science. It is argued here that designing for implementation and testing effects on implementation strategies can be considered as an important additional feasibility aspect that should not be ignored, since this offers foundational knowledge that could help across each phase of the research translational process (Craig et al., 2008). Further work could specify the implementation strategy in more

detail. For example, if the intervention is attempting to get people to engage in exercise behaviour, consideration of the implementation strategies would be to ask, what further education or instruction is needed for recipients of the intervention? What do recipients of the intervention need to know concerning the intervention (i.e., if telehealth, access to the equipment; if an aerobic/strength programme access to equipment)? How long or how often should they exercise (dose/fidelity), or how much support should be provided? What economic considerations influence the use of implementation strategies to deliver the intervention? Knowing this information will facilitate identifying what the barriers are to making this intervention happen. If Theme 4 (implementation strategy) is considered within feasibility studies that have yet to establish efficacy, one would need to consider our next theme on those intended to deliver the intervention long-term since by now, one would have gained prior knowledge of the barriers as well as facilitators for those delivering and receiving the intervention that could be passed onto those intended to deliver the intervention (e.g., identifying possible training needs of clinicians/research staff to deliver the program) for efficacy or effectiveness phases (see Theme 5). This also leads to better estimates of the costs involved for running a RCT. For example, when training needs are identified, these costs have to get covered by for example a research grant. These items can thus be added to the study budget.

#### ***Theme 5: Identify Those People Delivering the Intervention in the Research Trial/Efficacy Effectiveness/Hybrid Stages?***

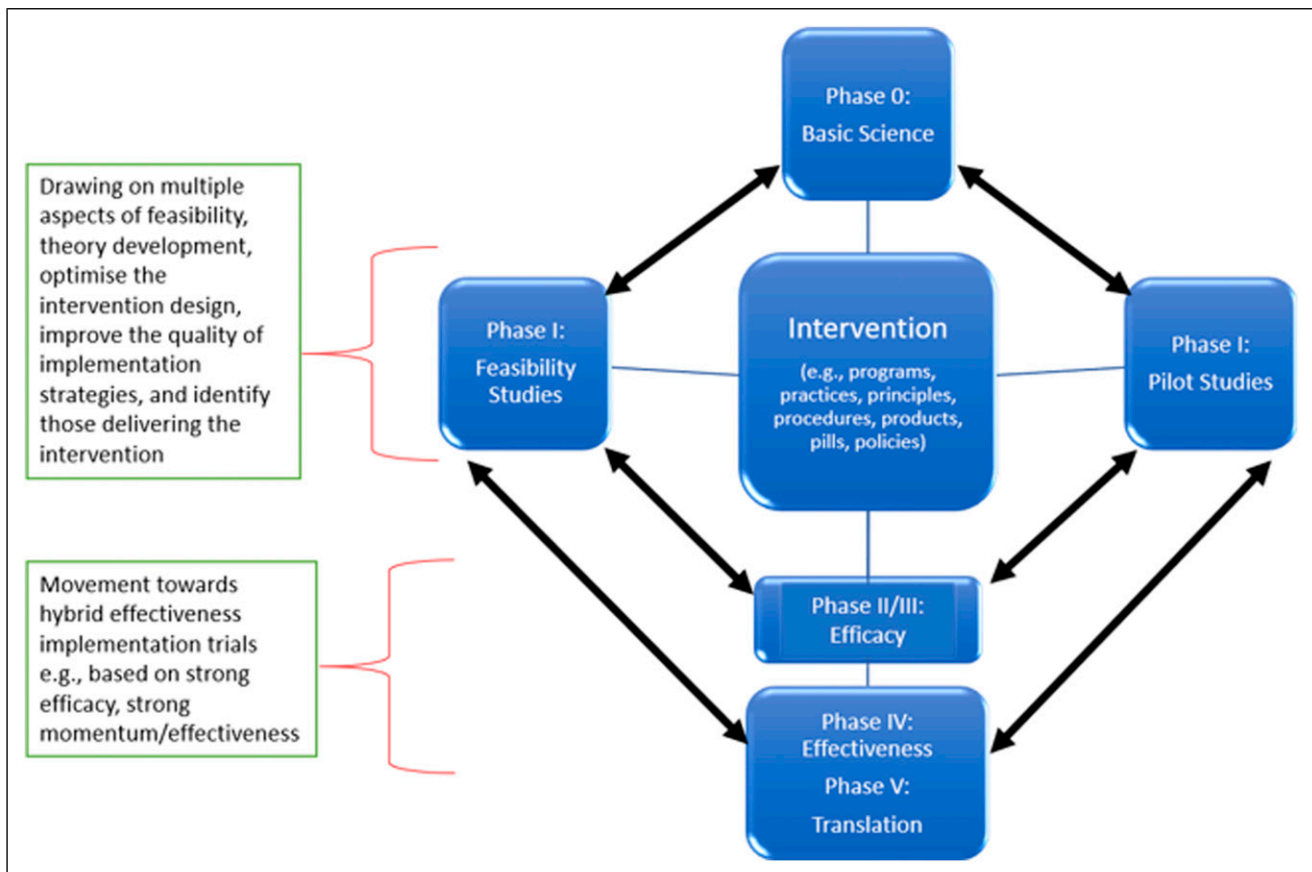
The case examples show that staff/primary therapists were identified in the MINC trial and coaches (physiotherapists, exercise physiologists student exercise physiologists) in BASE suggesting evidence over how, by who and for whom. However, often within research feasibility trials, key propositions are not identified, or identified for use within later Phase II or III or are identified and not being documented (e.g., in GEMS ‘the who’ was postgraduate and postdoctoral exercise scientists and physiotherapists who were delivering the intervention, yet this is not documented within the actual protocol or results papers) (Learnmonth et al., 2017). Equally important is to consider what skills and qualifications are needed to deliver the intervention to recipients of the intervention? Not collecting this data is also a lost opportunity. Yet again, within research trials, this is seldom documented or part of this process. Typical of most interventions at the feasibility phase, intervention designers do not anticipate or provide clear specification of who the intended people are to deliver the intervention and sustain it over time in real-world settings. Still, literally, these people may not even exist within the system that the intervention is intended to be provided. If groups or individuals to deliver the intervention do not exist in

the system that we intend it to go, how is a research study considered feasible at this phase?

It is clear from the above, as people adopt exercise behaviour for rehabilitation, we gain more information on the types of barriers and facilitators that follow. This is critical information because by specifying and operationalising how the implementation strategies should look like and what they should include (Theme 4), we can subsequently move towards who delivers it (Theme 5). For who ultimately delivers these implementation strategies in RCT or effectiveness studies, we also ensure for whom they will be delivered (Knox et al., 2018). By applying our themed findings from the current case studies (See Case Studies Table 1), implementation science clearly has a critical role in feasibility research because we could improve current feasibility research by helping to map out those individuals who could ultimately take on these roles (Chambers, 2012; Presseau et al., 2019; Wandersman et al., 2008) and this could further inform later phases (efficacy and effectiveness). Hence, we could optimise this aspect within feasibility studies before leading to efficacy and effectiveness where continued optimisation may ensue.

Our new model view, shown in Figure 2, builds the necessary scaffolding around the use of feasibility of a study from an implementation science lens and opens up and extends the idea of an iterative cyclical approach toward implementation science within feasibility studies to improve results later on (i.e., better choices over implementation strategy and therefore better results later on) (Davies et al., 2010).

Evidence indicates that researchers face a myriad of challenges translating the benefits of exercise in MS identified in clinical trials into increased physical activity and exercise participation. These challenges may stem from the methodological design. Our presented findings on theories, models and frameworks, combined with acceptability, feasibility, from the implementation science field at the feasibility phase can be used to improve effective translation in MS exercise interventions (Learmonth & Motl, 2018; Rapport et al., 2022). Our study is timely and provides a wider applicability by providing a roadmap to MS studies that are having to alter, adapt and optimise intervention designs amid on-going change such as a result of external factors as with the COVID-19 pandemic (Chambers, 2020; Sandroff et al., 2021; van der Groen et al., Unpublished).



**Figure 2.** Proposing a cyclical model on where feasibility meets implementation science to improve translating and implementing evidence into practice.

Our findings represent a cyclical iterative approach (Hill & Knox, 2022; Knox et al., 2018), where we can learn about the possible implementation challenges at the feasibility phase and optimise the intervention throughout the translational process. We provide clarity for studies across the translational process by considering multiple case examples using different document sources highlighting where feasibility meets implementation science for studies that are yet to show strong efficacy or effectiveness. One limitation of our study is that guidelines on document analysis methodology is scant because document analysis is an underused qualitative methodology (Morgan, 2022). However, document analysis methodology and the use of standalone documents sourced (peer-reviewed published and unpublished documents) are very reliable data sources, and this was a far more cost-effective and time-efficient and unobtrusive process that could track change and development (Bathmanathan et al., 2018; Morgan, 2022). Document analysis can capture where feasibility meets implementation science in ways that other qualitative methods may not be able to. We highlight the use of the integration of implementation strategies and optimisation processes at the feasibility phase (and beyond), showing how our documents sources reveal this practice, although our case examples have yet to show strong efficacy or effectiveness. We also presented critical reflection to describe where feasibility meets implementation science amid on-going change. This further allowed for clarity related to the opportunities and challenges faced, including the foundations of implementation science in multiple areas of feasibility studies. The premise of this paper was that if the intervention has not yet shown strong efficacy or effectiveness, feasibility studies should be employed, and the earlier implementation science is introduced the better. The well-constructed implementation of behaviour change will improve real-world practice (Campbell et al., 2000; Friedman et al., 2015; Learmonth & Motl, 2018). Therefore, the development of solutions on how implementation science can complement feasibility studies is sorely needed within the translational process literature and how this can improve the quality of implementation strategies (how to effectively implement and sustain those interventions) in effectiveness research, potentially answering the question to why MS exercise research is currently not translating to real-world participation.

## Conclusion

To maintain clarity in research translation within exercise and MS, we need to understand the intersection between feasibility and implementation science outlined here in terms of the need of theory, models, frameworks, acceptability, implementation strategies and evaluation. These crucial aspects highlighted in our document sources also clearly identified the importance of gaining prior knowledge of the barriers as well as facilitators for those delivering the intervention that could be passed onto those intended to deliver the intervention long-term in real-world

practice across different settings and systems. Hence, our key message is that there is potential for an iterative process whereby feasibility studies help us learn about refining implementation strategies and, optimise and adapt aspects so that we can harness all of this prior knowledge to influence later phases with the continued importance to on-going development optimisation and adaption to diverse populations and systems.

## Appendix

### Abbreviations

|         |  |
|---------|--|
| CFIR    | Consolidated Framework For Implementation Research                 |
| GEMS    | Guidelines for Exercise in MS                                      |
| MRC     | Medical Research Council   |
| MINC-MS | Motor Improvement in Neurological Conditions in multiple sclerosis |
| MS      | Multiple Sclerosis   |
| RCT     | Randomised Controlled Trials                                       |

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