A pilot study to evaluate the efficacy of an at-home TheraPutty® hand exercise intervention on strength and function in adults with inclusion body myositis

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Abstract

Objective

Inclusion body myositis (IBM) is the most common idiopathic inflammatory myopathy after age 50, causing progressive weakness of quadriceps and finger flexors. With no effective disease-modifying therapies, accessible non-pharmacological strategies are needed. Exercise is safe, may slow disease progression and improve strength. However, most studies focus on lower limb strengthening, despite hand strength being vital to independence. Our study analysed the acceptability, tolerability and efficacy of an at-home TheraPutty® hand exercise intervention on grip strength and function in adults with IBM.

Methods

In this 12-week, single-arm pilot study, thirteen participants underwent baseline, 6-week, and 12-week assessments of grip/pinch strength (hand-held dynamometry), dexterity (Nine-Hole Peg Test, Box and Block Test), and function (IBM Functional Rating Scale, Duruöz Hand Index). Use of intention-to-treat and per-protocol approaches assessed the effect of adherence on strength outcomes. Adherence (≥75% sessions), acceptability, and tolerability were assessed through weekly diaries and an end-of-study questionnaire.

Results

Nine participants (69%) achieved ≥75% adherence. Intention-to-treat analysis showed no significant changes in grip or pinch strength, although Box and Block performance improved significantly bilaterally. In the per-protocol analysis, significant improvements were observed in non-dominant 2-point and bilateral 3-point pinch strength. Fatigue, pain, and difficulty using even the lowest resistance TheraPutty® limited adherence. Overall, participants rated the programme as moderately acceptable (mean 3.5/5) and tolerable (3.4/5).

Conclusion

A home-based TheraPutty® programme is feasible and generally acceptable in IBM, with potential signals of benefit among adherent participants. Future larger, longer-term studies should refine treatment protocols to reduce fatigue and optimise efficacy.

Key words

inclusion body myositis, sporadic, exercise therapy, hand strength

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Introduction

Idiopathic inflammatory myopathies (IIM) are rare group of autoimmune disorders characterised by skeletal-muscle inflammation (1). Inclusion body myositis (IBM) is the most common IIM after age 50 and shows a male predominance (1, 2). The prevalence varies between countries, though it affects an estimated 16-70 individuals per million in Caucasian populations (3). Clinically it features a distinctive, often asymmetric pattern of weakness, preferentially impacting the quadriceps, deep finger flexors and bulbar muscles, leading to falls, impaired grip and dysphagia (2). Disease course is heterogeneous but typically spans a decade or more; many patients require a walking aid within ~5 years and progress to wheelchair dependence in advanced stages, with substantial impacts on independence and quality of life (2).

The selective weakness in finger flexor muscles [flexor digitorum superficialis (FDS), flexor digitorum profundus (FDP) and flexor pollicis longus (FPL)] distinguishes IBM from other myopathies (4). These muscles are crucial for fine motor tasks such as writing, cutting food, holding objects. Furthermore, this muscle group declines more rapidly in the first year after diagnosis than other muscle groups measured by manual muscle testing (MMT) and dynamometry scores (4). Given this impact on daily independence, interventions specifically targeting hand strength and function are particularly relevant.

The pathogenesis of IBM remains an active area of research. Current evidence suggests that persistent inflammation mediated by cytotoxic $CD8^+$ T cells plays a central role in disease pathology. The observation of a-synuclein accumulation within muscle fibres has further suggested that IBM involves both inflammatory and degenerative mechanisms (5). Despite these insights, conventional immunomodulatory therapies have not demonstrated disease-modifying benefit, though several therapeutic trials remain under investigation which may show promise for future treatment options (6). Supportive rehabilitation therefore remains the mainstay of care (1, 2). Pragmatic non-pharmacological strategies that preserve muscle strength, function and daily independence represent a critical unmet need.

Exercise is increasingly considered safe and potentially beneficial in people with inflammatory myopathies (6-16) and may exert anti-inflammatory effects via myokines such as interleukin-6 (17). Previous studies in dermatomyositis, polymyositis and IBM have demonstrated that appropriately prescribed resistance and aerobic exercise programmes can improve or maintain muscle performance, aerobic capacity and physical function without worsening disease activity (7-17). In IBM specifically, small studies suggest resistance training may improve or stabilise lower-limb strength and mobility outcomes, although findings remain heterogenous and are limited by small sample sizes, short intervention periods and variable exercise protocols (7, 11, 13, 14, 16).

Importantly, much of the existing rehabilitation literature in IBM has focused on lower-limb strengthening, aerobic conditioning, or generalised exercise approaches. Many prior interventions have also relied heavily on specialised gym-based equipment such as leg press machines, limiting accessibility and long-term feasibility for patients with progressive disability (10, 12-16). Comparatively little attention has been directed toward hand-specific rehabilitation despite selective deep finger-flexor weakness being one of the defining and most functionally disabling features of IBM (2, 4, 16).

In 1998 Felice *et al*. were the first group to report differences in strength between dominant and non-dominant sides suggesting that targeted exercise may play a role in delaying disease progression (18). Where weakness has progressed to the point where participation in a formal exercise programme has become difficult, the use of a power enhancing glove shows promise in improving impaired hand function (19). Although emerging technologies may play a role in the future, the role of exercise shortly after diagnosis needs to be encouraged to maintain strength and function for as long as possible (20).

Evidence examining structured hand exercise interventions aimed at preserving strength and function earlier in the disease course remains limited. Given the chronic progressive nature of IBM, accessible home-based exercise interventions that support long-term adherence are particularly important. Previous studies suggest home exercise programmes are feasible and well tolerated in IBM populations (8, 11), though targeted hand rehabilitation strategies remain underexplored.

TheraPutty® (Fabrication Enterprises Inc) is a medical-grade, malleable putty which provides a simple, scalable way to load finger flexors with task-relevant movements (21). TheraPutty® is available in six different colour coded resistance grades ranging from XX-soft (tan) to X-firm (black). In both osteoarthritis and rheumatoid arthritis populations, such programmes have improved grip strength and endurance without adverse effects (22, 23). The putty is inexpensive, small and portable, making it a practical option for prescribing to IBM patients as an at-home exercise tool. To the authors' knowledge, no study has assessed the acceptability and tolerability of TheraPutty® in IBM. Evaluating these factors alongside its effect on strength and function is essential to determine its suitability in this unique population.

This pilot study therefore aims to evaluate the effectiveness and acceptability of a 12-week intensive 'at home' TheraPutty® hand exercise regimen on hand strength and function in IBM patients. It is hypothesised that this programme will improve hand strength and function over the 12-week test period, while maintaining adequate patient acceptability and tolerance. Findings are intended to inform the design and outcome selection of a future statistically powered controlled trial.

Methods

Overall study design

This is a 12-week, single-arm, pilot study evaluating a predominantly home-based TheraPutty® hand-exercise programme for adults with IBM.

The study protocol was developed with involvement of consumers from the Myositis Research Consumer Panel (24), a collaboration between the Myositis Discovery Programme and Myositis Association Australia, to ensure that the proposed protocol and treatment regime was appropriate and accessible for IBM patients.

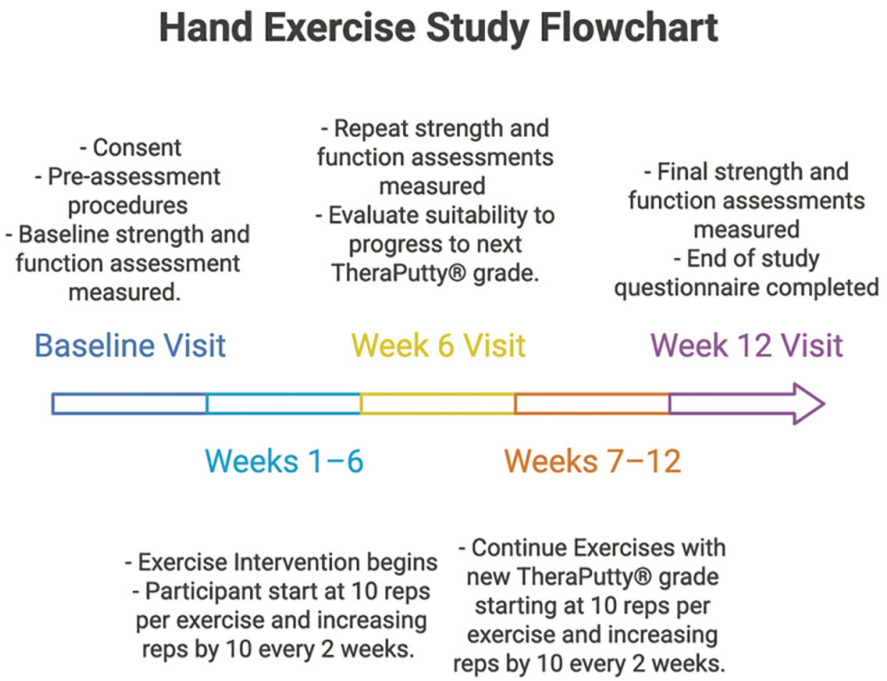

Fig. 1. Flowchart of hand exercise study procedures over the 12-week intervention.

Participants

Participants were recruited through the Myositis Specialist Clinic at the Perron Institute and the Myositis Discovery Programme at Murdoch University/Perron Institute: both specialist centres in IBM care. Recruitment was based on participant self-selection following invitation to participate. Potential participants were identified via a research mailing list or routine appointments and invited to participate. Interested individuals underwent screening for eligibility according to the predefined inclusion and exclusion criteria before enrolment. Patients were eligible for inclusion if they met the following criteria: aged 18 years or older; able to read and understand English; confirmed diagnosis of IBM by a neuromuscular specialist; and able to manipulate TheraPutty® with at least one hand. Patients were excluded based on the following criteria: injury, recent surgery, or another condition that limited their ability to undergo strength testing or exercise; if the sponsor-investigator considered participation unsafe; any allergy or sensitivity to TheraPutty® ingredients (silicone polymer); enrolled in another trial that might interfere with study outcomes; or if they were actively completing, or had recently (within the past three months) completed, a structured hand-exercise programme. Recruitment remained open for ~2 months. As a pilot, no minimum sample size was determined and all eligible patients expressing interest were enrolled.

Baseline visit

A summary of the study protocol from Baseline visit to week 12 of study is outlined in Figure 1.

Baseline visits occurred at Murdoch University, Perron Institute or off-site if required. Following consent, demographic and clinical data were collected from medical records, including handedness, diagnosis details, and disease duration. Participants also self-reported their use of mobility aids and any history of joint pain or prior hand injuries.

Baseline hand strength and function were then assessed in the following order:

- *Hand-held dynamometry.* Hand-held dynamometry (HHD) is the

current clinical standard for the objective assessment of muscle force in IBM and has been validated for use in neuromuscular populations (25, 26). The portable Citec Handheld Dynamometer was used to assess grip and pinch strength in this study (27). Grip strength was assessed with participants seated, shoulder adducted, elbow flexed at 90° unsupported, forearm in neutral, and wrist positioned at 0-30°, extension. Two trials were conducted per hand, beginning with the dominant side, and standardised instructions were provided: "Ready? Squeeze as hard as you can…Harder!...Relax." No practice trials were allowed for any of the grip measures assessed.

Pinch strength was assessed using the dynamometer with a pinch applicator, evaluating two-point, three-point, and lateral pinch grips. Owing to the risk of fatigue in smaller muscle groups, only one trial was conducted for each hand per grip. The assessor demonstrated each grip prior to testing, emphasising correct finger placement (fingertip pressure for two- and three-point pinch; radial aspect of the index finger and thumb for lateral pinch).

- *Nine-Hole Peg Test*. The Nine-Hole Peg Test (9-HPT) is a validated measure of finger dexterity in neuromuscular conditions (28). Participants were instructed to place and remove nine pegs into a pegboard as quickly as possible, with the total time in seconds recorded. One practice trial was permitted prior to formal testing, which was conducted first with the dominant hand and then the non-dominant.
- *Box and Blocks Test*
  The Box and Blocks Test (BBT) is a reliable and valid assessment of gross manual dexterity across multiple patient groups (29). Participants were asked to move blocks across a partitioned box from one side to the other over a period of 60 seconds. The total number of blocks transferred in 1 minute is the recorded outcome. Each participant was provided with a demonstration and a 15-second practice before testing commenced, beginning with the dominant hand.
- *Duruöz Hand Index*
  The Duruöz Hand Index (DHI) is a validated, self-reported questionnaire assessing activity limitations related to hand function in musculoskeletal and rheumatological conditions (30). It consists of 18 items spanning domains such as kitchen tasks, dressing, hygiene, office work, and other daily activities. Items are rated on a likert scale ranging from 0 ("without difficulty") to 5 ("impossible"), producing a total score between 0 and 90, with higher scores indicating greater functional impairment.
- *IBM Functional Rating Scale*
  The IBM Functional Rating Scale (IBMFRS) is a clinician-administered, disease-specific instrument validated for use in IBM populations to assess functional limitations in activities of daily living (31). The tool includes 10 items, each scored on a Likert scale from 0 (unable to perform) to 4 (normal). The summed score ranges from 0 to 40, with higher values reflecting better functional ability.

Exercise intervention

Following baseline assessment, TheraPutty® (six grades) was prescribed by a physiotherapist based on the highest grade allowing the patient to make a full fist, with fingers touching palm. If unable to do so, participants received the softest grade (XX soft -tan colour). Participants were then educated on the hand exercise programme via an instructional video. The intervention was designed as a predominantly home-based exercise programme, with participants completing exercises independently in their own home environment following initial instruction from a study physiotherapist. No routine supervised exercise sessions were conducted between assessment visits. The exercise programme included warm-up activities and four structured TheraPutty® hand exercises outlined in Figure 2. Each participant received an A4 handout with a 12-week habit tracker to help with compliance and recording of exercise completion, any missed sessions or altered repetitions, and deviations from the schedule. This compliance information was provided to the study team via Weekly Study Diary reporting. At the baseline visit, participants were directly supervised while demonstrating each exercise to confirm correct technique, safe performance, and understanding of the prescribed programme before commencing independent home exercise.

Weekly electronic diaries were sent to participants starting from 7 days after the baseline visit (via REDCap). Adherence monitoring was performed remotely through these weekly diaries, which captured exercise frequency, repetitions completed, TheraPutty® grade used, missed sessions, and reasons for missed sessions. Study staff reviewed diary responses weekly to identify potential adherence concerns or adverse symptom responses. A participant was said to be fully compliant with the study if they reported completing ≥75% of the 3 x weekly exercise sessions over the 12 weeks (*i.e*. at least 27 out of 36 sessions).

Each week, perceived exertion was also assessed via a visual analogue Borg scale ranging from 6 (no exertion at all) to 20 (Maximal exertion) (32). Adverse events were recorded in free text form within the diary via asking patients if they had any health or symptom changes to report that week.

Week 6 and Week 12 visit. At Week 6 (Allowing up to +14 days after week 6 for flexibility) dynamometry, dexterity, and functional outcome assessments were repeated. The physiotherapist repeating the tests did not access previous scores to avoid potential bias. At Week 6, exercise technique, diary completion, and adherence were reviewed by a physiotherapist, with retraining if necessary. This review acted as the primary structured supervision point during the intervention period. Participants were assessed for suitability to progress to the next TheraPutty® grade, with advancement prescribed unless contraindicated. With the increase in grade of TheraPutty®, the participants would reduce their repetition count to 10 reps and then increasing repetition count by 10 each fortnight as per week

Fig. 2. Primary hand exercises constituting the intervention using TheraPutty®.

1-6. This exercise protocol is summarised in Figure 3. If it was deemed inappropriate for participants to progress to the next TheraPutty® grade, they were told to continue doing 30 repetitions for the next 6 weeks. At Week 12 (±7 days), outcome measures were repeated, alongside the End-of-Study Questionnaire.

End of study-questionnaire. An end of study questionnaire captured participant perspectives on the programme through 14 questions adapted from a questionnaire developed by Sekhom *et al*. (33). Using a 5-point Likert scale, the survey assessed programme acceptability (4 items), tolerability (4 items), perceived benefit (2 items), and the impact on hand pain where applicable (1 item). This survey is included in the Supplementary material.

Study objectives. The efficacy of the exercise intervention was determined through comparing the change between baseline, 6-week and 12-week timepoints across the strength, dexterity and functional measures.
The secondary objective of the study was to evaluate the acceptability and tolerability of the programme via self-report and exercise plan adherence. Additionally, the impact of adherence (≥75%) on changes in strength and function were explored.

Analysis. Both an intention to treat and a per protocol approach were used in analysis. In the per-protocol approach, ≥75% adherence to the total number of sessions was the cut-off for inclusion in analysis. Pre/post change was assessed via one-way ANOVA with *post-hoc* testing via paired samples t-test. Exploratory analyses compared outcomes between adherence subgroups. Statistical significance was defined as $p<0.05$ (95% confidence level) for all analyses. Statistics from diaries and questionnaires informed acceptability and feasibility.

Ethics. Ethical approval was obtained from Murdoch University Human Research Ethics Committee (HREC-2025-069) prior to study commencement. The trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12625000379415p). All procedures follow the approved protocol, Good Clinical Practice (33) and the principles of the Declaration of Helsinki.

Results

Fourteen participants were recruited. One participant, who had debilitating weakness in their finger flexors at baseline withdrew from the study after the first week due to difficulty with the exercises. This left 13 participants for whom complete data is presented.
The cohort was predominantly male (69%), with a mean age of 72.1 years

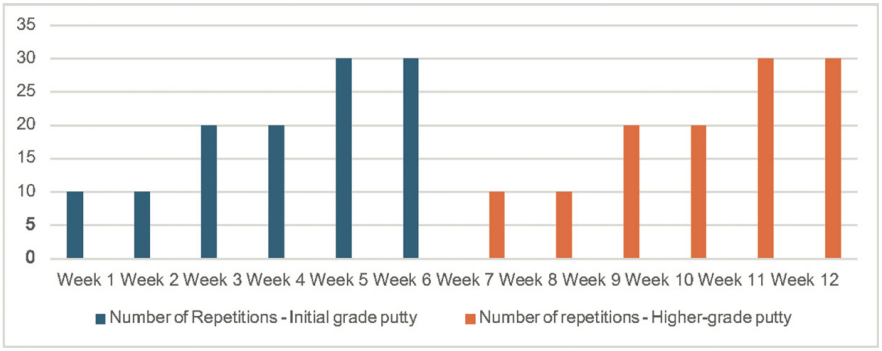

Fig. 3. Repetitions per exercise of the programme using TheraPutty® across the 12-week intervention.

(SD=11.4). The mean age at diagnosis was 65.3 years (SD=9.8), with an average disease duration of 13.3 years (SD=7.7) prior to trial involvement, indicating a cohort with longstanding disease. Baseline IBMFRS scores demonstrated moderate functional impairment overall (mean 24.2, SD=7.3; range 12-37). In respect to mobility at time of enrolment, eight participants used mobility aids (three used walking sticks, three used four-wheel walkers, and two used powered wheelchairs), while the remaining participants were independently ambulant. Baseline FDP weakness was present across the cohort (mean MMT 6.1/10, SD=2.4). All participants were right-hand dominant.

TheraPutty® allocation at baseline included 10 participants receiving XX soft (tan colour) putty, one receiving yellow (X-soft), and two receiving red (soft). Three did not progress to higher resistance levels. Nine of the 13 (69%) met ≥75% compliance. For non-compliant participants, common reasons for missed sessions included illness and hand-related symptoms (muscle fatigue, pain, discomfort). Mean Borg exertion score for the exercise sessions across all twelve weeks was 13.9 (st dev = 3.13), corresponding to "Somewhat Hard to Hard".

Outcome measures

All data for strength, dexterity and function tests, at baseline, 6 weeks and 12 weeks, are presented in Table I below. In the intention-to-treat analysis, grip strength did not change significantly for either hand, nor did 2-point, 3-point, or lateral pinch strength. Performance on the 9-hole peg test also remained stable. However, Box and Blocks scores improved significantly for both hands. *Post-hoc* paired t-tests showed a significant difference between both baseline and 12 weeks (p=0.002) as well as 6 weeks to 12 weeks (p=0.008) in the non-dominant hand and only a significant difference between baseline and 12 weeks in the dominant hand (p=0.005). Patient-reported outcomes, including the DHI and the IBMFRS, did not change significantly. The trend of means over the three time points for each outcome measure in the intention to treat group is illustrated in Figure 4.

In the per-protocol analysis (≥75% adherence), grip strength did not change significantly over the 12 weeks. However, selected pinch grip measures improved, with the non-dominant 2-point pinch and both non-dominant and dominant 3-point pinch showing statistically significant gains. Post hoc

Table I. Mean ± standard deviation values for all outcome measures and corresponding **p** values from one-way repeated-measures ANOVA.

	Intention to Treat Analysis				**Per Protocol Analysis - ≥75% of sessions completed for full compliance**			
Outcome (dominant: D, non-dominant: ND	**Baseline**	**Week-6**	**Week 12**	***p*-value - One way ANOVA**	**Baseline**	**Week-6**	**Week-12**	***p*-value - One way ANOVA**
Hand-held dynamometry								
Grip strength (D, N)	73.7± *48.1*	61.9 ± *28.4*	64.8 ± *32.0*	0.375	60.6 ± *31.6*	60.0 ± *29.6*	65.1 ± *34.6*	0.105
Grip strength (ND, N)	68.3 ± *48.6*	55.3 ± *45.0*	57.8 ± *42.4*	0.349	61.1 ± *42.1*	58.6 ± *51.6*	61.5 ± *46.2*	0.657
2-point pinch (D, N)	15.4 ± *8.5*	14.0 ± *8.2*	15.9 ± *7.8*	0.483	15.4 ± *8.4*	14.8 ± *9.3*	16.9 ± *8.8*	0.236
2-point pinch (ND, N)	14.5 ± *10.5*	12.7 ± *11.3*	16.1 ± *11.9*	0.137	14.7 ± *10.7*	13.7 ± *12.9*	17.3 ± *13.4*	**0.023***
3-point pinch (D, N)	30.8 ± *15.0*	27.3 ± *14.5*	33.3 ± *15.8*	0.368	29.9 ± *12.6*	28.9 ± *16.4*	35.8 ± *17.0*	**0.049***
3-point pinch (ND, N)	27.5 ± *17.4*	23.8 ± *15.8*	28.3 ± *17.4*	0.34	26.7 ± *16.9*	25.2 ± *18.2*	31.3 ± *18.8*	**0.01***
Lateral pinch (D, N)	30.8 ± *15.7*	20.8 ± *9.0*	27.1 ± *11.1*	0.125	30.5 ± *15.9*	22.3 ± *9.9*	29.2 ± *11.6*	0.283
Lateral pinch (ND, N)	29.2 ± *18.3*	20.3 ± *12.4*	26.0 ± *11.0*	0.258	29.8 ± *19.5*	21.6 ± *14.2*	27.4 ± *12.3*	0.544
Dexterity								
9-hole peg test (D, Sec)	30.7 ± *10.3*	31.2 ± *8.6*	30.4 ± *11.8*	0.947	40.9 ± *29.6*	36.0 ± *15.1*	36.3 ± *16.2*	0.463
9-hole peg test (ND, Sec)	37.7 ± *26.5*	34.4 ± *13.4*	34.4 ± *14.9*	0.522	31.9 ± *11.2*	31.5 ± *9.9*	32.6 ± *12.7*	0.614
Box & Block (D, n. of blocks)	45.7 ± *7.8*	45.7 ± *6.8*	51.5 ± *9.3*	**0.002***	43.3 ± *7.9*	45.9 ± *6.6*	48.2 ± *9.3*	**0.007***
Box & Block (ND, n. of blocks)	44.8 ± *7.5*	46.6 ± *5.9*	49.5 ± *8.9*	**0.006***	44.0 ± *8.0*	44.0 ± *7.1*	49.4 ± *9.3*	**0.03***
Patient-reported functional scores								
DHI (total score)	20.4 ± *15.5*	21.9 ± *18.9*	23.8 ± *19.5*	0.158	21.8 ± *16.2*	23.8 ± *18.7*	25.0 ± *20.0*	0.296
IBM-FRS (total score)	24.2 ± *7.3*	23.2 ± *7.8*	24.6 ± *7.2*	0.411	23.2 ± *7.0*	21.8 ± *7.2*	23.4 ± *6.8*	0.639

* Asterisks and highlighting indicate statistically significant differences (p<0.05).

analysis using paired t-test showed a significant difference between 6 weeks to 12 weeks for non-dominant 2-point pinch (p=0.004), non-dominant 3-point pinch (p=0.01) and dominant 3-point pinch grip (p=0.02) respectively). Dexterity findings were mixed: 9-hole peg performance was unchanged, while the Box and Blocks test indicated a significant improvement for the dominant hand only. Post hoc analysis located the significant difference between week 6 and 12 in the dominant hand box and blocks test (p=0.04). Patient-reported outcomes did not demonstrate meaningful change, although there was a non-significant trend towards increased disability on the DHI. The trend of means over the three time points for each outcome measure in the per protocol group is illustrated in Figure 5.

Acceptability and tolerability

All participants completed the end of study questionnaire and overall, participants rated the programme positively. The programme was regarded as generally acceptable and tolerable by participants with a mean Likert score of 3.52 out of 5(SD=0.65) and 3.37 (SD=0.8) respectively. Furthermore, the participants perceived the programme to be beneficial to their condition, with a mean Likert score of 3.54 (st dev=0.75). Four out of the thirteen participants reported hand pain as an existing symptom at baseline. These four participants reported that their pain was worsened by the exercise protocol with a mean Likert score of 3.5 (SD=1.29) indicating their pain was between 'stayed the same' and 'somewhat worse'.

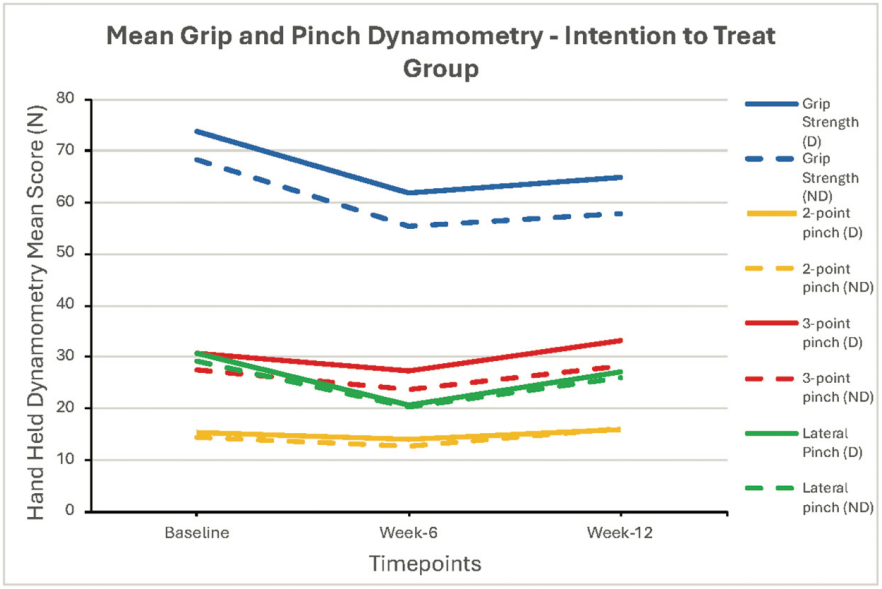

Fig. 4. Mean (± standard deviation) hand-held dynamometry scores for each outcome measure across Baseline, Week 6, and Week 12 in the intention-to-treat (ITT) cohort.

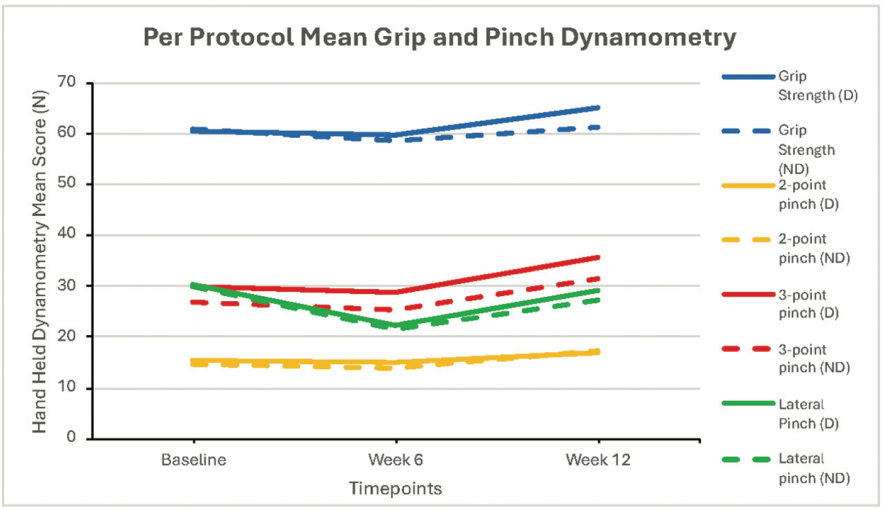

Fig. 5. Mean (± standard deviation) hand-held dynamometry scores for each outcome measure across Baseline, Week 6, and Week 12 in the per-protocol (PP) cohort comprising participants fully adherent to the 12-week TheraPutty® exercise programme.

Discussion

This pilot study evaluated the feasibility, acceptability and efficacy of a 12-week, home-based TheraPutty® hand exercise programme in individuals with IBM.

In the per-protocol analysis, compliant participants demonstrated significant improvement in multiple pinch grip measures, including non-dominant 2-point and both dominant and non-dominant 3-point pinch strength. These findings show that targeted resistance exercise can enhance strength in deep finger flexor muscles when adherence is maintained.

Notably, gains were more evident in the non-dominant hand. This may reflect a greater "training reserve" in muscles less maximally recruited in daily activities, providing greater capacity for measurable adaptation. In contrast, the dominant hand is habitually more engaged in functional tasks and may have been operating closer to its physiological ceiling, limiting the potential for strength gains (35). This asymmetry aligns with prior literature demonstrating preferential strength improvements in less-affected or less-utilised muscle groups among individuals with IBM (8, 18).

The trajectory of strength outcomes consistently showed an initial decline at week 6 followed by improvement by week 12. This pattern was unexpected, as early phases of resistance training typically yield rapid strength gains due to neural adaptation. During neuromuscular re-education, multiple levels of the neuraxis become more efficient through improved motor-unit synchronisation, increased firing rates, and reduced antagonistic co-activation

(36-38). Though these effects were not observed in the present cohort.

The transient decline in the early weeks likely reflects early fatigue effects. Muscle fatigue can result from metabolic disturbances such as hydrogen ion accumulation, impaired sarcoplasmic-reticulum Ca^{2+} release, and oxidative stress (39). These processes may be exacerbated by IBM-related chronic inflammation, $CD8^{+}$ T-cell infiltration, mitochondrial dysfunction, and impaired protein homeostasis (40). Consequently, participants in week 6 may have been tested on already fatigued muscle groups during their weekly training cycle, producing the apparent declines mid programme; though it should be noted that these were rarely statistically significant.

The subsequent improvement between week 6 and 12 may reflect delayed structural and metabolic adaptation. Hypertrophic changes in myofibrils are likely to have contributed to gains, alongside exercise-induced modulation of inflammatory and anabolic signalling. Exercise has been shown to upregulate anti-inflammatory cytokines and increase growth factors such as IGF-1, facilitating myogenic repair even in chronically inflamed tissue (41). These findings offer a plausible mechanism for the significant strength gains observed among adherent participants.

Compared with earlier IBM exercise studies, these results are encouraging and broadly consistent with the growing body of literature supporting exercise as safe and potentially beneficial in inflammatory myopathies. Trials by Spector *et al*. and Arnardottir *et al*. demonstrated that resistance and home-based exercise interventions could be undertaken without evidence of disease exacerbation, although measurable strength gains were limited (7, 8). Subsequent studies incorporating aerobic and resistance-based approaches reported improvements in exercise capacity, muscle performance, and preservation of function in IBM and other inflammatory myopathies (9-17). In particular, the longer-duration home exercise programme reported by Alemo *et al*. demonstrated improvements in muscle strength and exercise performance after 16 weeks and again following longer-term resistance training interventions, supporting the concept that clinically meaningful adaptation in IBM may require prolonged intervention periods (11, 14). Our findings align with these observations, with strength improvements emerging primarily between weeks 6 and 12 rather than during the early intervention phase.

Importantly, most prior IBM exercise studies have focused predominantly on lower-limb strengthening, aerobic conditioning, or blood-flow-restricted resistance training using specialised equipment (7-16). While these approaches have shown promise, they may be less accessible for individuals with advanced disability or limited access to supervised rehabilitation services. In contrast, the present study evaluated a simple, low-cost, home-based intervention specifically targeting the deep finger flexors, which are among the earliest and most functionally disabling muscle groups affected in IBM (2, 4). This focus on hand-specific rehabilitation represents an important distinction from previous literature and addresses a clinically meaningful gap, given the major contribution of hand weakness to loss of independence in activities such as eating, dressing, and writing.

The present findings also extend broader exercise literature in idiopathic inflammatory myopathies. Studies in dermatomyositis and polymyositis have demonstrated that appropriately prescribed exercise can improve aerobic capacity, muscle performance, and quality of life without increasing inflammatory disease activity (7, 17). Collectively, these findings support the emerging paradigm that exercise should be considered a core supportive therapy across inflammatory myopathies, including IBM, rather than avoided because of concerns regarding muscle damage or overwork weakness. However, the present study also highlights that exercise prescription in IBM requires careful individualisation, particularly in relation to fatigue management, resistance selection, and disease severity.

The absence of significant change in the intention-to-treat analysis likely reflects suboptimal adherence. Qualitative comments revealed that many participants found even the lowest TheraPutty® grade (XX-Soft Tan) difficult, reporting that "Tan has probably too much resistance for my hand" and "cannot squeeze [the tan putty] enough to close [my hand]." Rather than disengagement or forgetfulness, non-compliance stemmed from disease-specific barriers such as fatigue, pain and task difficulty. This distinction highlights that participants remained motivated but were physically limited by disease-related impairments.

Future programmes should therefore emphasise individualised resistance levels, potentially incorporating softer materials. Furthermore, recruiting participants at earlier disease stages, prior to severe atrophy, may enhance responsiveness to rehabilitative interventions. Narrower inclusion criteria focusing on those with preserved baseline function could yield clearer outcomes in future trials.

Despite the challenges described, participants found the intervention to be acceptable and generally tolerable based on the end of study questionnaire. This is encouraging for the potential of future, larger cohort studies focusing on hand interventions like this one in the IBM population.

Although DHI scores worsened slightly, this divergence from objective strength gains may reflect heightened awareness of impairment, or on-going muscle fatigue. Some participants felt they were "too far gone" to see improvement, suggesting the intervention heightened insight into deficits. Alternatively, exercise-related fatigue may have transiently worsened perceived function, resulting in poorer DHI scores (42).

Encouragingly, Box and Block test performance improved bilaterally in the intention-to-treat analysis, suggesting potential benefit in dexterity or coordination. However, practice effects cannot be excluded and are common in these assessments (43). Longer-term evaluation is required to confirm whether these gains represent meaningful functional change.

This study was limited by its small sample size (n=13) and short duration (12 weeks), constraining statistical power, the ability to control for covariates and

the ability to detect subtle effects. The absence of a control or comparison group also further limits the interpretation of results and distinguish intervention effects. The recruitment strategy may also have introduced selection bias, as patients who were more motivated to exercise and more health literate were more likely to take part, potentially limiting the generalisability of results within the broader IBM population.

For a future study, extending the intervention to 6-12 months may better capture the slower adaptations typical of IBM and allow for a gradual increase in exercise intensity, necessary to reduce the influence of transient fatigue. Testing should be protocol-defined to occur ≥48 hours after the preceding exercise session to avoid acute fatigue confounding. Further adaptations in methodology are also needed to reduce participant burden and expand recruitment approaches to reduce bias and increase sample size. Measurement variability could be reduced by use of softer resistance materials and strategies to mitigate external influences such as ambient temperature, which was found to significantly alter putty viscosity and resistance. Any future studies may also benefit from use of additional outcome measures such as ultrasound and quantitative MRI of the forearm muscles to detect objective measures of change. These methods have been used in interventional studies, although primarily in the lower limbs (44).

Conclusion

This pilot study demonstrates that a home-based TheraPutty® programme is feasible and acceptable for individuals with IBM, with signals of efficacy among adherent participants. The observed late-phase strength improvements, particularly in non-dominant hands, support the biological plausibility of exercise-induced adaptation even in a degenerative myopathy. However, difficulties with fatigue, pain and excessive resistance underscore the need for modified materials and protocols tailored to this population. Larger, longer-term studies are vital to confirm efficacy and optimise usability in clinical practice.

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