Original research

Clinical outcomes and economic impact of a digital telemedicine intervention in patients with functional motor disorders: a single-blind, randomised controlled trial

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ABSTRACT

Background Functional motor disorders (FMD) cause long-term disability and economic burden. There is a need for multidisciplinary interventions to manage both motor and non-motor symptoms. We aim to evaluate the clinical and economic effects of integrating digital telemedicine into multidisciplinary FMD management.

Methods This single-blind, randomised controlled trial involved patients with FMD. They were randomly assigned to receive 5-day multidisciplinary rehabilitation with either a digital telemedicine or a standard care programme. The digital telemedicine group received remote management and wearable sensors. A blinded evaluator assessed primary and secondary outcomes at baseline, post-treatment, 12-week and 24-week follow-ups. The primary outcomes were changes in motor symptoms. The secondary outcomes were changes in non-motor symptoms, quality of life (QoL) and mobility in unsupervised settings. The incremental cost-effectiveness ratio (ICER) and quality-adjusted life years (QALYs) were calculated at 24 weeks.

Results Of the total of 62 patients, half made up the digital telemedicine group (n=31, 40.82% female, mean age 42.55±12.65 years) and half the standard care group (n=31, 59.18% female, mean age 43.77±14.44 years). The mental QoL score for the standard care group was lower (p=0.045) and declined compared with the digital telemedicine group (p=0.034), with lower scores at follow-up (p=0.03). At 24 weeks, the ICER (€5503/QALY) showed that digital telemedicine, despite higher initial costs, yielded 0.037 additional QALYs and reduced healthcare use during follow-up.

Conclusions Despite similar improvements in motor symptoms in both groups, digital telemedicine offers an effective adjunct to maintain mental health QoL and reduces healthcare costs in the long-term management of FMD.

Trial registration number ClinicalTrials.gov ID: NCT05345340.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Functional motor disorders cause long-term disability and economic burden.

WHAT THIS STUDY ADDS

⇒ Our evaluation of the clinical outcome and economic impact of digital telemedicine in patients with functional motor disorders shows that it can offer an effective adjunct to maintain mental health–related quality of life and reduce healthcare costs in the long-term management of FMD, despite similar improvements in motor symptoms in both groups.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study provides evidence for the integration of digital telemedicine into routine care for patients with FMD and for its potential to improve mental health long-term outcomes, quality of life and reduce healthcare costs.

INTRODUCTION

Patients with functional motor disorders (FMD), a subset of functional neurological disorders (FND), present with motor (eg, limb weakness, tremors, dystonia, gait/postural control disorders) and non-motor (eg, cognitive impairments, pain, fatigue) symptoms, associated with long-term disability and high healthcare costs.[1–6] FMDs are highly prevalent in neurological settings, affecting an estimated 10–15% of patients.[7]

Recent advancements have furthered our understanding of the pathophysiology underlying FMD, in which body-mind interactions are disrupted within a predictive coding framework.[8 9] For example, altered internal models and brain network dysfunctions, notably limbic system overactivity which advises a perception of voluntariness to involuntary movements.[8] These mechanisms give rise to diverse symptoms (weakness, tremors, dystonia, gait disturbances) and substantial disability.[6 8]

Evidence supports tailored, multidisciplinary treatment within a biopsychosocial framework to enhance functional recovery and quality of life (QoL); indeed, rehabilitation is a cornerstone of FMD management.[8 10] A recent multicentre randomised controlled trial (RCT) demonstrated that specialist physiotherapy improved motor symptoms (59% vs 38%) and enhanced mental

health, social functioning and anxiety outcomes compared with standard care.[11] No statistically significant differences in physical functioning, as measured with Short Form-36 (SF-36), were observed at 12 months postrandomisation, however.[11] This lack of objective improvement has fuelled ongoing debate and uncertainty about the optimal therapeutic approach to FMD. Innovative, targeted approaches are needed to bridge the gap between subjective improvement and objective clinical outcomes in FMD management.

Digital tools integrated with telemedicine may improve outcomes by enabling long-term remote monitoring and individualised care in unsupervised settings, thus potentially reducing healthcare costs.[12 13] Preliminary evidence from two observational studies suggests that telemedicine, either as a standalone intervention or integrated into multidisciplinary protocols, may bring medium-term rehabilitation benefits such as reduced motor symptom severity and fatigue in FMD.[11 12] These findings require confirmation through fully powered randomised trials.

With the present single-blind RCT, we wanted to evaluate the clinical effects and economic impact of integrating digital telemedicine into multidisciplinary FMD management, with a focus on changes in motor and non-motor symptoms, health perception and healthcare costs. Our hypothesis was that when supported by digital devices, telemedicine may enhance multidisciplinary care and foster self-management, improve QoL and optimise healthcare resource utilisation.

METHODS

Study design and participants

This single-blind, parallel-arm RCT was registered on clinicaltrials.gov (ID NCT05345340). Reporting followed the Consolidated Standards of Reporting Trials and Consolidated Health Economic Evaluation Reporting Standards.[14 15] Blinded assessors evaluated primary and secondary outcomes at baseline (T0), postrehabilitation (T1), 12-week (T2) and 24-week (T3) follow-ups. Cost-effectiveness was calculated at T3.

Consecutive patients were recruited from Neurologic Unit B, University Hospital of Verona (Italy), between April 2022 and March 2024. Inclusion criteria were: age ≥18 years, confirmed FMD diagnosis,[16] Mini-Mental State Examination[17] score ≥24, at least one motor symptom (ie, tremor, weakness, spasms, dystonia, gait, balance disorders), access to a smartphone/computer and basic digital literacy. Exclusion criteria were: dissociative seizures as the predominant symptom, severe cognitive/physical impairments, discontinuation of the 5-day rehabilitation intervention, incomplete data or lack of consent.

Ethical considerations

The study adhered to the Declaration of Helsinki and Good Clinical Practice guidelines. Ethics approval was granted by the local committee (Comitato Etico per la Sperimentazione Clinica delle Province di Verona e Rovigo Project Number: 3695CESC). Patients signed the written informed consent form at enrolment.

Randomisation

Patients were randomised 1:1 via a web-based system (www.randomisation.org) to receive either a digital telemedicine intervention (DTi, experimental group) or standard care (control group). Only the principal investigator had access to the randomisation list.

Study procedures and interventions

Patients completed a 5-day, 2 hour/day rehabilitation programme in person at Neurologic Unit B (University Hospital of Verona, Italy) to restore normal movement patterns within a multidisciplinary framework following validated protocols.[18–20] On completion of the programme, the patients were allocated to receive the DTi or standard care for 24 weeks.

Digital telemedicine intervention

The intervention consisted of a coadjuvant 24-week telemedicine programme incorporating remote telemedicine home-based sessions (30 min/session, 1 session/week, 24 weeks) and self-management sessions (1 hour/session, 2 sessions/week, 24 weeks) to empower their self-management strategies. A telemedicine platform (PHOEMA GPI PLATFORM, Trento, Italy) was used to handle scheduling, notifications and data tracking. The patients received a wearable device (Polar Vantage M, Polar Electro, Kempele, Finland) for monitoring remote activity and to record unsupervised activity at T1, T2 and T3 in 5-day monitoring phases (online supplemental Table 1).

Standard care

Standard care consisted of 24 weeks of self-management home-based sessions (1 hour/session, 3 sessions/week, 24 weeks) without telemedicine support.[20]

Outcome measures

Patient demographics (age, sex) and clinical history (motor and non-motor symptoms onset, disease duration, neurological, psychiatric or medical comorbidities, previous organic diagnosis) were collected at enrolment.[6] Inperson assessment included primary and secondary outcomes.

Primary outcome

The primary outcome measure was changes in motor symptom severity and duration, as measured with the objective-rated Simplified Functional Movement Disorders Rating Scale (range, 0–54; higher scores indicate more motor symptoms) collected at T0, T1, T2 and T3.[21]

Secondary outcomes

The secondary outcomes were changes in fatigue and pain (T0, T1, T2, T3), QoL, alexithymia, anxiety, depression (T0, T2, T3) and perception of change (T1, T2, T3).[18] The Multidimensional Fatigue Inventory Scale (MFI-20) was applied to assess fatigue, differentiate between general and physical fatigue, decreased motivation and activity and mental fatigue (subscale range, 4–20; higher scores mean more perceived fatigue).[22] The Brief Pain Inventory was applied to measure pain intensity (subscale range, 0–40; higher scores mean more intense pain) and interference (subscale range, 0–70; higher scores mean greater pain interference in daily activities).[23] The Toronto Alexithymia Scale-20 evaluated the ability to identify, recognise and express emotions (range, 20–100; higher scores mean more difficulties).[22] The Beck Depression Inventory (range, 0–63, higher scores mean more depressive symptoms), and the Beck Anxiety Inventory (range, 0–63, higher scores mean more anxiety symptoms) were applied to measure depression and anxiety, respectively.[24 25]

The self-rated Mental Health and Physical Functioning scale of the 12-item Short-Form Health Survey evaluated QoL (SF-12, range, 0–100; higher scores mean better mental and physical health).[26] The 7-point Clinical Global Impression (CGI) scale evaluated the self-rated perception of change after treatment (from 1–very much improved to 7–very much worse).[27]

Unsupervised assessment

The wearable device synchronised data via the device flow platform to capture step count, activity duration, caloric expenditure and sleep patterns for asynchronous review. Measures of feasibility were the number of days worn and problems with synchronising the devices.

Economic impact

Healthcare resource utilisation was measured via a questionnaire based on the Institute for Medical Technology Assessment (iMTA) Medical Cost Questionnaire.[28] Data collection covered the period from T0 to T3. Participants provided retrospective self-reports of healthcare utilisation, including specialist and general practitioner visits, diagnostic tests, hospitalisations, rehabilitation services and physiotherapy.[1 2] To ensure consistency, trained researchers administered the survey and standardised follow-up procedures without differentiating between the intervention and the control group. Costs were categorised as direct healthcare costs and intervention-specific costs.[1 2] Direct healthcare costs included expenditures for managing FMD, such as specialist visits, diagnostic procedures and rehabilitation services.[1 2] The costs were calculated based on current Italian healthcare reference tariffs, including diagnosis-related group rates for hospitalisation and outpatient services (Nomenclatore Tariffario Prestazioni Specialistiche Ambulatoriali). Intervention costs specific to the DTi were estimated using a bottom-up microcosting method.[29] The costs include materials, such as the telemedicine platform and wearable devices and the physiotherapist's time for data analysis (an estimated 10 min per session) and for conducting the telerehabilitation sessions (an estimated 20 min per session multiplied by hourly wage). In addition, outpatient physiotherapy service tariffs were used for comparative reference. Detailed cost calculations are given in online supplemental Table 2.

We derived quality-adjusted life years (QALYs) by mapping the SF-12 QoL scores into utility weights.[30]

Sample size and statistical analyses

A sample size of 56 patients was necessary, assuming $\alpha=0.05$ (probability of type 1 error) and an 80% power to detect a mean difference of 4.66 (standard deviation (SD) 5.2) in the primary outcome measure (S-FMDRS) using a test for two groups of pre-post scores (PASS V.14).[18] Assuming a 10% drop-out rate, 62 patients (31 per group) were necessary to perform the study.

Intention-to-treat analysis was the last observation carry forward method addressed missing data. Descriptive statistics (means and SD) were calculated and categorical variables analysed using the χ^2 test. The Shapiro-Wilk Test showed normal distribution. Two-way mixed ANOVA assessed clinical outcomes with Time (T0, T1, T2, T3) as a within-group factor and Group (DTi vs standard care) as a between-group factor, including their interaction (time×group). A two-tailed unpaired Student's t-test was used for between-group comparisons. Statistical significance was set at p value <0.05 and Bonferroni's correction was applied for multiple comparisons. Statistical analysis was performed using JASP (V.0.15).

For the economic analysis, we computed the incremental cost-effectiveness ratio (ICER) by dividing the incremental cost by the incremental effect (QALY gain at 24 weeks) between the two groups. Bootstrap analyses with 10 000 simulations estimated the probability of DTi being cost-effective compared with standard care based on a willingness-to-pay (WTP) threshold of €30 000 per QALY in Italy. The ICERs were calculated from a healthcare perspective, including intervention and direct healthcare costs using both microcosting and regional National Health System reference costs; this resulted in two distinct ICERs. As the time horizon was 24 weeks, discounting was not applied.[31 32]

RESULTS

Of the 152 patients assessed for eligibility, 62 were randomly assigned to receive either DTi (n=31) or standard care (n=31). Three patients from each group were lost to follow-up (drop-out) (figure 1). No adverse events or safety concerns were observed. Table 1 presents sample demographics and clinical characteristics.

Between-group analysis revealed no significant differences in age (p=0.723), disease duration (p=0.840), motor and non-motor symptoms (all, p>0.05) and comorbidities (all, p>0.05). Fewer women (p=0.005) and more dystonic symptoms were noted in the DTi group (p=0.046) than in the standard care group. Baseline outcome measures showed no significant between-group differences (online supplemental Table 3).

Primary outcome

No significant main effect of group or time×group interaction was observed, indicating similar changes in both groups over time. Post-hoc tests revealed a significant main effect of time ($F(3) = 34.561$, $p<0.001$), with improvements from T0 to T1, T2 and T3 (all $p<0.001$) (table 2).

Secondary outcomes

A significant group effect was observed for mental QoL scores, which were lower in the standard care than in the DTi group ($F(1) = 4.172$, $p=0.045$). There were no significant group differences for fatigue, pain, depression, anxiety, alexithymia or physical QoL. Patient-reported perception of change at the CGI showed no significant differences (tables 2–4).

There was a significant time×group interaction for mental QoL scores ($F(2) = 3.464$, $p=0.034$), with a decline from T2 to T3 in the standard care group (p=0.032), which were lower than those recorded for the DTi group at T3 (p=0.03). No other significant interaction effects were observed (tables 2–4).

As regards the time effect, fatigue dimensions improved considerably: general ($F(3) = 25.758$, $p<0.001$), physical ($F(3) = 34.120$, $p<0.001$) and mental fatigue ($F(3) = 3.885$, $p=0.01$), reduced activity ($F(3) = 14.255$, $p<0.001$) and motivation ($F(3) = 7.707$, $p<0.001$). An improvement in general and physical fatigue was observed at all follow-ups, while mental fatigue scores decreased from T0 to T1. Reduced activity and motivation improved initially but then worsened by T3 (p=0.049 and p=0.001, respectively). Pain interference decreased from T0 to T1 (p=0.005) but worsened at T3 (p=0.027) ($F(3) = 4.659$, $p=0.004$). Pain intensity remained unchanged. Depression ($F(2) = 4.155$, $p=0.018$) and anxiety ($F(2) = 15.761$, $p<0.001$) scores decreased over time, with the greatest decreases recorded at T2 and T3 (all $p<0.001$). Alexithymia improved from T0 to T2 ($F(2) = 4.807$, $p=0.007$). Physical QoL improved from T0 to T2 and T3 ($F(2) = 19.863$, $p<0.001$; all $p<0.001$) (tables 2–4).

Unsupervised assessment

Usable data were collected from 29/31 (93.5%) DTi group patients at T1, 18 (58.1%) at T2 and 14 (45.2%) at T3. Missing data were due to: incorrect device usage (n=2) at T1; device unavailability (n=2) or patient dropout (n=3) at T2; improper use of the device or failure to synchronise it correctly (n=14)

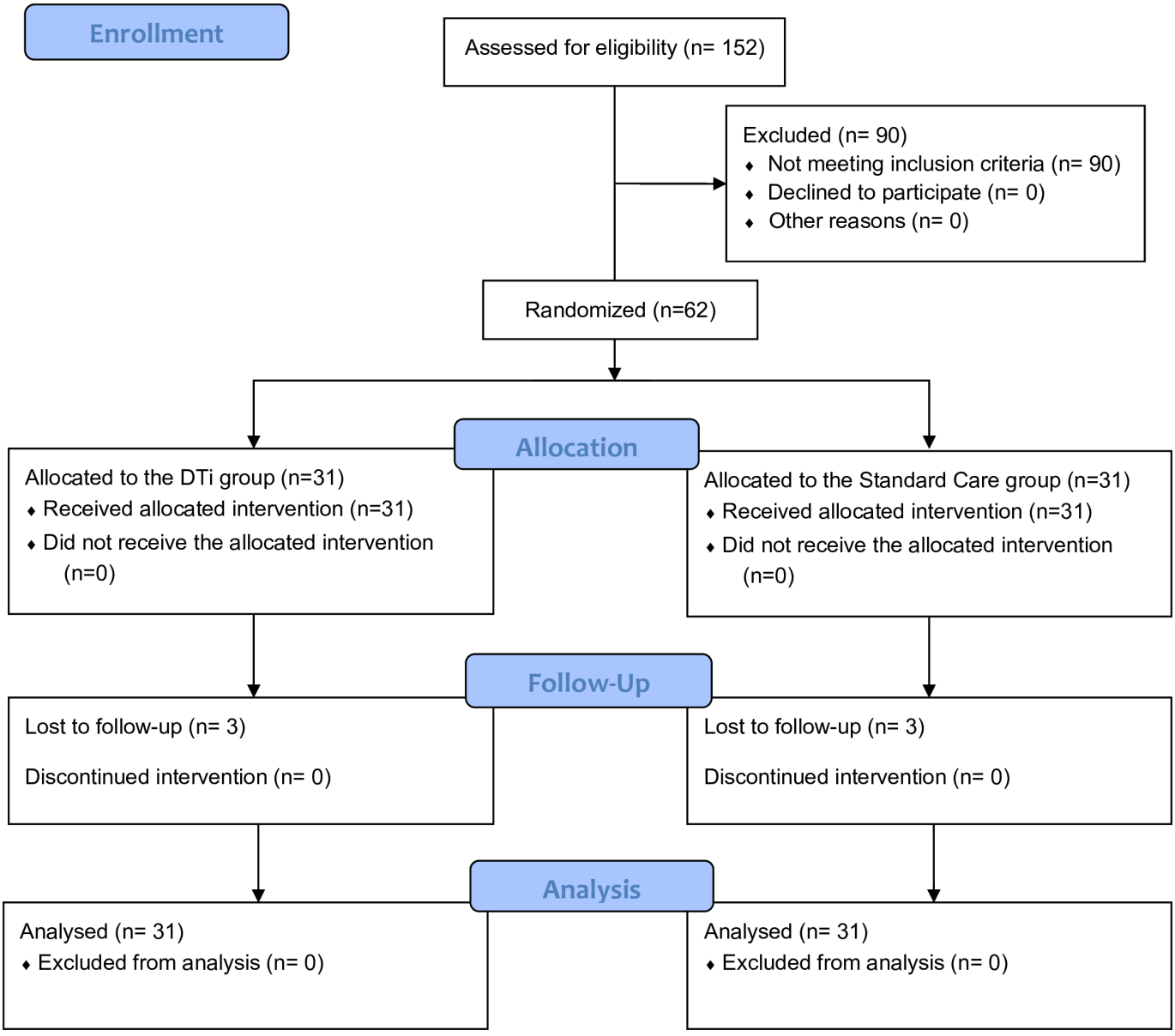

Figure 1 Study flow chart. DTi, digital telemedicine intervention.

at T3. Online supplemental table 4 presents the data on daily activity time, step count, caloric expenditure and sleep duration.

Economic impact

Healthcare costs

The total healthcare costs for the DTi group were approximately €229 compared with €607 for the standard care group. This difference was not statistically significant (p=0.15), however (table 5). The main difference between the two groups could be attributed to the costs for specialist visits and rehabilitation: the mean cost for specialist visits was €31.62 for the DTi group and €66.76 for the standard care group (p=0.08); the mean cost for rehabilitation was €120.90 for the DTi group and €473.00 for the standard care group (p=0.08). Most rehabilitation costs were for physiotherapy. The cost breakdown for the DTi group was €384.68 for physiotherapy versus €104.41 for the standard care group (p=0.21), €35.55 for instrumental visits versus €22.13 for the standard care group (p=0.73) and €40.58 for the general practitioner fees versus €45.50 for the standard care group (p=0.9).

Intervention costs

The average intervention costs per participant were €282, as determined by bottom-up microcosting, and €582 calculated using the regional fee schedule (Nomenclatore Tariffario). The average cost for a DTi group patient was approximately €511 or €811 based on the regional tariff versus €607 for a standard care group patient.

Cost and QoL

The intervention's impact on QoL and costs was assessed relative to standard care. The incremental effect was 0.037 QALYs. According to the bottom-up microcosting method, the incremental cost was −€99.38, resulting in an ICER of −€2675.93/QALY, meaning that the DTi was less expensive than standard care (table 6). Bootstrapping analysis revealed an 85%

Table 1 Patient demographics and clinical characteristics at baseline before entering the 5-day inperson rehabilitation programme

	All patients (n=62)	DTi (n=31)	Standard care (n=31)	Between-group analysis,P
Mean age, years (±SD)*	43.1 (13.48)	42.55 (12.65)	43.77 (14.44)	0.723
Women, no. (%)†	49 (79.03)	20 (40.82)	29 (59.18)	0.005‡
Mean duration symptoms, years (±SD)*	8.3 (4.1)	3.81 (4.35)	4.49 (3.9)	0.840
Clinical characteristics–no. (%)				
Motor symptoms				
Tremor	*39 (62.9)*	*20 (64.52)*	*19 (61.29)*	*0.793*
Weakness	*48 (77.42)*	*25 (80.65)*	*23 (74.19)*	0.544
Dystonia	17 (27.42)	12 (38.71)	5 (16.13)	**0.046‡**
Myoclonus	11 (17.74)	4 (12.9)	7 (22.58)	0.319
Facial disorders	12 (19.35)	4 (13.9)	8 (25.81)	0.199
Gait impairments	47 (75.81)	23 (74.19)	24 (77.42)	0.767
Parkinsonism	8 (12.9)	6 (19.35)	2 (6.45)	0.130
Tics	6 (9.68)	3 (9.68)	3 (9.68)	1
Voice disorders	17 (27.42)	7 (22.58)	10 (32.26)	0.393
Swallowing disorders	13 (20.97)	7 (22.58)	6 (19.35)	0.755
FMDs phenotype†				
Isolated	5 (8.06)	2 (6.45)	3 (9.68)	0.641
NMSs†				
Reported fatigue	44 (70.97)	22 (70.97)	22 (70.97)	1
Reported chronic pain	46 (74.19)	23 (74.19)	23 (74.19)	1
Previous organic disease/comorbidities†§				
Neurological disease	20 (31)	11 (34)	9 (28)	0.79
Psychiatric disease	9 (14)	3 (9)	6 (19)	0.47
Medical disease	34 (53)	16 (50)	18 (56)	0.80

*For statistical tests: two sample independent t-test.
†χ^2 test, Fisher's exact test.
‡$p<0.05$.
§Patients could have one or more organic disease/comorbidities.
DTi, digital telemedicine intervention; FMDs, functional motor disorders; NMSs, non-motor symptoms.

probability that the DTi was cost effective when the WTP was set at €30 000. When we used the outpatient tariff for rehabilitation sessions, the incremental cost was €200.41, resulting in an ICER of €5503/QALY, meaning that the DTi was more expensive than standard care; however, the ICER was lower than the Italian cost-effectiveness threshold of €30 000/QALY. There was a 78% probability of the DTi programme being cost-effective in this case. Ultimately, this suggests that the DTI was cost-effective. Caution is warranted when interpreting the results owing to the high degree of uncertainty in the probability of being cost-effective, as shown by the bootstrapping analysis. This uncertainty was primarily due to the small sample size.

DISCUSSION

The most notable finding of our study is the lack of deterioration in mental QoL scores for the DTi group, despite both groups exhibiting similar improvements in motor and non-motor symptoms. At 24 weeks, the ICER (€5503/QALY) indicated that despite higher initial costs, DTi yielded additional health benefits (0.037 QALYs) and significantly reduced healthcare service utilisation during follow-up.

Telemedicine provides innovative approaches to managing movement disorders and allows for regular objective symptom assessment and treatment adherence in real-world settings.[33 34] Indeed, it broadens access to specialised care through telemonitoring, teleconsultation, tele-education and teletreatment.[35] Previous studies report acceptable feasibility, cost and time savings, patient and physician satisfaction and outcome and impact on morbidity and QoL.[33]

Ours is the first study to integrate digital technologies into a coadjuvant telemedicine programme for patients with clinically definite FMD. Although this limits direct comparison,[36] parallels can be drawn with previous research, nonetheless.

Compared with our earlier observational study, where the telemedicine group showed greater improvements in motor symptoms (S-FMDRS), physical fatigue (MFI-20) and self-rated change (CGI) after a 5-day rehabilitation treatment followed by 12 weeks self-management, the current RCT did not demonstrate the superiority of the adjunctive DTi for motor and non-motor outcomes. The key difference we believe lies in the mental QoL scores: no significant improvements were previously observed in either its physical or mental components (SF-12), whereas the current RCT demonstrated a notable benefit in the mental domain. This discrepancy likely reflects the differences in study design, since both studies used the same measures. The more rigorous RCT design provided stronger evidence, minimising biases inherent to observational studies.[18]

Indeed, our findings are shared by a multicentre phase 3 RCT involving 355 FMD patients in England and Scotland. The trial compared specialist physiotherapy (nine sessions plus follow-up) with standard care (referral to local neurological physiotherapy). Like our results, no statistically significant effects were observed in the physical functioning domain (SF-36) at 12-month follow-up. However, better mental health scores were

Table 2 Primary and secondary clinical motor and non-motor outcomes at baseline, postrehabilitation and follow-up assessments

	T0		T1	T2			T3		
	Mean (SD)		Mean (SD)	Mean (SD)			Mean (SD)		
Outcome	DTi	TAU	DTi	TAU	DTi	TAU	DTi	TAU	Mixed ANOVA
S-FMDRS (0–54)	17.0 (7.74)	14.93 (9.17)	8.83 (8.82)	8.51 (10.06)	6.19 (7.66)	7.48 (7.75)	6.67 (7.91)	8.58 (7.88)	Group p=0.198 Time p<0.001 T×G p=0.912
MFI-20									
General fatigue (4–20)	14.77 (4.00)	15.48 (3.78)	9.77 (4.74)	9.96 (4.16)	11.03 (4.86)	11.35 (4.19)	11.64 (4.95)	13.09 (4.82)	Group p=0.427 Time p<0.001 T×G p=0.745
Physical fatigue (4–20)	14.58 (4.17)	16.00 (3.49)	9.51 (4.91)	9.80 (4.17)	10.45 (4.91)	10.41 (4.92)	10.51 (4.92)	12.32 (4.72)	Group p=0.332 Time p<0.001 T×G p=0.367
Reduced activity (4–20)	12.12 (4.55)	13.45 (3.95)	8.09 (4.26)	10.64 (4.13)	9.48 (4.15)	10.22 (4.95)	9.87 (4.60)	11.90 (4.46)	Group p=0.062 Time p<0.001 T×G p=0.405
Reduced motivation (4–20)	8.29 (3.81)	8.22 (3.95)	6.19 (3.45)	6.29 (3.13)	6.61 (3.51)	7.19 (3.76)	7.03 (3.29)	9.12 (3.84)	Group p=0.331 Time p<0.001 T×G p=0.113
Mental fatigue (4–20)	12.00 (4.56)	11.35 (4.54)	9.32 (4.51)	9.74 (4.15)	10.41 (4.82)	9.87 (4.88)	10.35 (4.37)	11.38 (5.15)	Group p=0.940 Time p=0.010 T×G p=0.534
BPI									
Intensity (0–40)	17.64 (14.77)	15.38 (14.76)	14.61 (10.96)	14.28 (13.09)	14.06 (11.76)	13.54 (11.91)	16.35 (13.65)	14.45 (13.71)	Group p=0.655 Time p=0.288 T×G p=0.890
Interference (0–70)	23.03 (18.15)	22.74 (20.88)	13.32 (14.39)	16.71 (20.42)	20.35 (19.83)	16.64 (18.25)	21.67 (20.89)	21.61 (25.15)	Group p=0.968 Time p=0.004 T×G p=0.501

*Statistically significant; P value adjusted for multiple comparisons.
ANOVA, analysis of variance; BPI, Brief Pain Inventory; DTi, digital telemedicine intervention; MFI-20, Multidimensional Fatigue Inventory-20; S-FMDRS, Simplified Functional Movement Disorders Rating Scale; T0, before rehabilitation; T1, post-treatment; T2, 12-week follow-up; T3, 24-week follow-up; TAU, treatment as usual; T×G, time×group interaction.

Table 3 Depression, anxiety, alexithymia and quality of life scores at baseline, postrehabilitation and follow-up assessment

Outcomes	T0 Mean (SD)		T2 Mean (SD)		T3 Mean (SD)		
	DTi	TAU	DTi	TAU	DTi	TAU	Mixed ANOVA
BDI-II (0–63)	8.548 (8.233)	12.452 (8.824)	7.516 (7.220)	7.935 (6.821)	6.774 (5.737)	11.613 (7.944)	Group p=0.054 Time p=0.018 T× G p=0.058
BAI (0–63)	18.097 (10.058)	22.871 (10.987)	14.484 (9.798)	15.677 (9.928)	13.387 (9.344)	18.419 (10.449)	Group p=0.112 Time p<0.001 T× G p=0.122
TAS-20 (20–100)	43.258 (14.227)	48.839 (11.716)	39.710 (11.396)	44.452 (11.664)	41.871 (13.150)	45.677 (12.494)	Group p=0.098 Time p=0.010 T× G p=0.788
SF-12 (0–120)							
Physical functioning	32.248 (13.314)	30.851 (10.603)	37.051 (13.476)	38.855 (12.809)	38.432 (14.401)	38.795 (11.159)	Group p=0.929 Time p<0.001 T× G p=0.435
Mental health	47.057 (11.172)	43.436 (13.775)	47.029 (11.755)	45.350 (9.813)	47.964 (9.988)	38.699 (12.429)	Group p=0.045 Time p=0.155 T× G p=0.034*

P value corrected for multiple comparisons.
*Statistically significant.
BAI, Beck Anxiety Inventory; BDI-II, Beck Depression Inventory; SF-12, 12-item Short-Form; TAS-20, Toronto Alexithymia Scale-20.

Table 4 Clinical global impression scores at post-rehabilitation and follow-ups

	T1 no. (%)		T2 no. (%)		T3 no. (%)		
CGI	DTi	TAU	DTi	TAU	DTi	TAU	Fisher's exact test
Improved	24 (77)	26 (84)	23 (74)	24 (77)	14 (14)	14 (14)	T1 p=0.19
No change	7 (23)	3 (10)	5 (16)	4 (13)	7 (23)	2 (6)	T2 p=1
Worsened	0 (0)	2 (6)	3 (10)	3 (10)	10 (32)	15 (48)	T3 p=0.16

Worsened: category includes minimally, much and very much worse.
No change: category includes no change.
CGI, Clinical Global Impression Questionnaire; DTi, Digital Telemedicine intervention; T1, post-treatment; T2, 12-week follow-up; T3, 24-week follow-up; TAU, treatment as usual.

reported among participants receiving specialist physiotherapy. The consistency suggests that structured therapeutic engagement, whether in person, digital or hybrid, primarily benefits the mental health component of QoL in FMD patients.[11]

Our findings hold two-fold importance. First, they demonstrate that multidisciplinary management, with structured diagnosis, patient education and rehabilitation, improves both motor and non-motor symptoms, such as fatigue, depression, anxiety and alexithymia, regardless of the DTi component.

Second, the differences in the mental QoL scores for the DTi group suggest that the intervention may have reduced feelings of abandonment and neglect commonly reported by FMD patients.[37] Continuous interaction through digital platforms and wearables may have created a sense of ongoing support, counteracting the perception of being left alone after initial rehabilitation. The DTi may also have enhanced patient engagement, motivation and coping strategies, which are known to improve psychological well-being in coping with chronic conditions.[38]

Moreover, the use of wearable devices may have helped bridge the gap between subjective experiences and objective findings for FMD, providing the patients with tangible insights into their daily activity.

Pick *et al* emphasised the need for consistent outcome measures in FND research, proposing a specific framework for FND that includes physical and psychological symptoms, life impact and economic aspects assessed through both clinician-reported and patient-reported tools. Following this approach, our study adopted a broad evaluation of treatment effects.[39] As in most FMD trials, we selected as the primary outcome a clinician-rated measure of motor symptom change (S-FMDRS).[39] The similar effect in clinician-rated outcomes despite a favourable trend in the patient-reported mental health suggests a disconnect between clinical assessments and patients' lived experience. This gap highlights the need to reconsider which outcomes best reflect meaningful change and disability in FND. As observed, emotional factors (such as anxiety, depression, dissociation and unhelpful illness beliefs) often influence symptom persistence and QoL, potentially more than motor severity alone.[40] These elements should therefore be central in future outcome development. A combined use of clinician-focused and patient-focused tools is essential to capture the full picture of recovery and ensure care remains patient-centred.

Despite data attrition over time, unsupervised assessment showed good initial acceptance of the DTi programme. The DTi group consistently surpassed the 10 000-step daily recommendation, averaging 6.32–7.23 km/day, suggesting that regular physical activity may have contributed to sustained mental well-being. Sleep duration also approached statistical significance, warranting further research into its potential impact on pain and fatigue. To date, no comparable long-term studies exist for FMDs, unlike other movement disorders or chronic conditions such as multiple sclerosis.[36]

The DTi reduced healthcare costs (€229 for DTi vs €607 for controls) by reducing the number of specialist visits and physiotherapy needs. The ICER based on microcosting was −€99. When tariff-based costs were applied, the ICER was €5416 per QALY, an index well below the €30 000/QALY threshold applied in Italy. In both cases, the DTi led to an improvement in clinical conditions and a reduction in costs, with an 85% probability using microcosting and a 78% probability using tariffs. This means that some patients exceeded the cost-effectiveness thresholds, suggesting not all FMD patients benefit equally. This variability raises a key question: which FMD patients may benefit most from telemedicine? A recent single-blind RCT evaluating a telemedicine intervention for fall prevention in Parkinson's disease reported cost-effectiveness especially for non-motor outcomes and accessibility.[34] Our previous before-after study involving 40 FMD patients also demonstrated sizeable reductions in healthcare utilisation costs.[1] When we compared the number of diagnostic tests, specialist visits, hospitalisations, emergency room visits and rehabilitation services 2 years before and after accurate diagnosis, we observed fewer unnecessary examinations and greater uptake of rehabilitation. Our data also underscore the importance of rehabilitative interventions for this complex

Table 5 Costs associated with healthcare resource utilisation over 24 weeks

Resource utilisation	TAU			DTi			Mixed ANOVA
	Patients – no. (%)	Visits – no.	Cost (€) Mean (SD)	Patients – no. (%)	Visits – no.	Cost (€) Mean (SD)	P value
General practitioner visits	11 (0.50)	37	45.50 (64.88)	10 (0.45)	33	40.58 (51.30)	0.9
Specialist visits	14 (0.64)	39	66.76 (93.30)	9 (0.41)	18	31.62 (74.14)	0.08
Instrumental visits	3 (0.14)	3	22.13 (57.02)	2 (0.09)	5	35.55 (116.69)	0.73
Rehabilitation	8 (0.36)	250	473.00 (963.25)	3 (0.14)	91	120.90 (344.21)	0.08
Physiotherapy	6 (0.27)	210	384.68 (784.58)	3 (0.14)	82	104.41 (303.28)	0.21
Total costs and emergency room visits			607.39 (1033.03)			228.65 (384.30)	0.15

DTi, digital telemedicine intervention; TAU, treatment as usual.

Table 6 Results of cost-effectiveness comparison: micro-costing versus standard tariff with ICER and cost-effectiveness probability

	No.	Incremental effect	Incremental costs	ICER	Probability cost-effectiveness, WTP €15000	Probability cost-effectiveness, WTP €30000
Microcosting	44	0.037	−99.38	−2685.93	83%	85%
Using the tariff for a rehab session	44	0.037	200.41	5416.58	69%	78%

ICER, incremental cost-effectiveness ratio; WTP, willingness to pay.

patient population from both clinical and economic standpoints. Identifying predictive markers of telemedicine success could optimise resource allocation and ensure that appropriate candidates are targeted.

The strengths of the present study lie in being the first RCT to integrate multidisciplinary management with digital telemedicine and remote monitoring in FMDs in a rigorous design, with 6-month follow-up, comprehensive clinical, QoL and economic assessments and the use of affordable, easy-to-use wearable devices. Thus, valuable insights may be gained for targeted interventions and future healthcare strategies. The study limitations are the long-term feasibility of remote monitoring, which was hampered by technical issues such as incorrect device use, synchronisation failures and logistic challenges in providing devices at follow-ups. The economic evaluation was also limited by the lack of assessment of indirect costs, such as productivity loss.

CONCLUSION

Despite similar improvements in motor symptoms in both groups, digital telemedicine may offer an effective adjunct to maintain mental health, QoL and reduce healthcare costs in long-term FMD management.

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