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Digital Physiotherapeutic Shoulder-Specific Training System for Patients with Shoulder Impingement: A Single-Center Noninferiority Randomized Controlled Trial

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Digital Physiotherapeutic Shoulder-Specific Training System for Patients with Shoulder Impingement: A Single-Center Noninferiority Randomized Controlled Trial

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Abstract

Background: Shoulder impingement is a common cause of shoulder pain. Standard management is supervised physiotherapy, but in-person rehabilitation may be limited by travel, cost, and scheduling barriers. Digital health solutions can deliver guided exercises remotely, potentially improving access and adherence.

Objective: To compare a 12-week home-based app-guided shoulder exercise program (DT group) with standard face-to-face physiotherapy (PT group), assessing clinical outcomes and cost-effectiveness.

Methods: This prospective, parallel-group RCT enrolled patients with shoulder impingement at a Shanghai orthopaedic center. Participants were randomized to 12 weeks of DT (app-based home exercise with daily sessions and weekly video supervision) or 12 weeks of standard PT (four supervised clinic sessions per week plus home exercises). The primary outcome was shoulder pain at rest on a 0–100 VAS; secondary outcomes included pain on activity (VAS), shoulder function (Constant–Murley score), health-related quality of life (SF-36), patient satisfaction, adherence, and total societal costs. Blinded physiotherapists assessed outcomes at 4, 12, and 24 weeks. We tested non-inferiority with a 1.0-point VAS margin (10 mm) and handled missing data by multiple imputation. Between-group differences over time were evaluated by linear mixed-effects models (with group, time, and interaction), applying Bonferroni correction for multiple comparisons. Cost-effectiveness was evaluated via incremental cost-effectiveness ratios using 1,000 bootstrap replicates.

Results: A total of 220 patients were randomized. Baseline characteristics were comparable between groups (all P>0.05). At 24 weeks (primary endpoint), mean pain-at-rest VAS had improved by 25.97 in DT vs 23.91 in PT (P=0.812). Pain-on-activity VAS improved by 28.35 vs 24.94 (P=0.558), and Constant–Murley score increased by 25.81 vs 24.38 (P=0.855). SF-36 physical-function scores improved slightly more in DT at 4–12 weeks (P<0.01) but were similar by 24 weeks; other SF-36 domains showed no meaningful differences. Patient satisfaction and adherence were high and similar in both groups (mean sessions/week 5.17 vs 5.15, P=0.848). Mean total cost per patient was lower in DT (¥44,306.69) than PT (¥54,853.65), an average saving of ¥10,546.

Conclusions: Home-based digital shoulder rehabilitation produced clinical improvements comparable to conventional physiotherapy. Both groups experienced similar reductions in pain and gains in shoulder function, supporting non-inferiority of the app-based program. Importantly, the digital intervention incurred lower overall costs while achieving similar outcomes, indicating it was more cost-effective than standard care. Clinical Trial: The trial was preregistered with the Chinese Clinical Trial Registry (https://www.chictr.org.cn/, registration number: ChiCTR2100042097; registration date: January 13, 2021)

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Digital Physiotherapeutic Shoulder-Specific Training System for Patients with Shoulder Impingement: A Single-Center Noninferiority Randomized Controlled Trial

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Abstract

Background: Shoulder impingement is a common cause of shoulder pain. Standard management is supervised physiotherapy, but in-person rehabilitation may be limited by travel, cost, and scheduling

barriers. Digital health solutions can deliver guided exercises remotely, potentially improving access and adherence. We conducted a single-center randomized trial in Shanghai to compare a 12-week home-based app-guided shoulder exercise program (DT group) with standard face-to-face physiotherapy (PT group), assessing clinical outcomes and cost-effectiveness.

Methods: This prospective, parallel-group RCT enrolled patients with shoulder impingement at a Shanghai orthopaedic center. Participants were randomized to 12 weeks of DT (app-based home exercise with daily sessions and weekly video supervision) or 12 weeks of standard PT (four supervised clinic sessions per week plus home exercises). The primary outcome was shoulder pain at rest on a 0–100 VAS; secondary outcomes included pain on activity (VAS), shoulder function (Constant–Murley score), health-related quality of life (SF-36), patient satisfaction, adherence, and total societal costs. Blinded physiotherapists assessed outcomes at 4, 12, and 24 weeks. We tested non-inferiority with a 1.0-point VAS margin (10 mm) and handled missing data by multiple imputation. Between-group differences over time were evaluated by linear mixed-effects models (with group, time, and interaction), applying Bonferroni correction for multiple comparisons. Cost-effectiveness was evaluated via incremental cost-effectiveness ratios using 1,000 bootstrap replicates.

Results: A total of 220 patients were randomized. Baseline characteristics were comparable between groups (all $P>0.05$). At 24 weeks (primary endpoint), mean pain-at-rest VAS had improved by 25.97 in DT vs 23.91 in PT ($P=0.812$). Pain-on-activity VAS improved by 28.35 vs 24.94 ($P=0.558$), and Constant–Murley score increased by 25.81 vs 24.38 ($P=0.855$). SF-36 physical-function scores improved slightly more in DT at 4–12 weeks ($P<0.01$) but were similar by 24 weeks; other SF-36 domains showed no meaningful differences. Patient satisfaction and adherence were high and similar in both groups (mean sessions/week 5.17 vs 5.15, $P=0.848$). Mean total cost per patient was lower in DT (¥44,306.69) than PT (¥54,853.65), an average saving of ¥10,546.

Conclusions: Home-based digital shoulder rehabilitation produced clinical improvements comparable to conventional physiotherapy. Both groups experienced similar reductions in pain and gains in shoulder function, supporting non-inferiority of the app-based program. Importantly, the digital intervention incurred lower overall costs while achieving similar outcomes, indicating it was more cost-effective than standard care.

Key words: Shoulder impingement; Exercise Therapy; Mobile Health; Randomized Controlled Trial.

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Background

Shoulder pain is highly prevalent worldwide, with studies reporting that about 16% of the general population experience shoulder pain at any given time[1]. Shoulder impingement syndrome is one of the most common underlying causes of shoulder pain, accounting for roughly 44%–65% of cases[2]. This condition often becomes chronic or relapsing, leading to long-term symptoms in many patients. Standard management of shoulder impingement is conservative, focusing on supervised physiotherapy. Physical therapy exercises aimed at strengthening the shoulder girdle and improving range of motion are considered the mainstay of treatment[2]. However, in-person rehabilitation can be limited by barriers such as travel distance, cost, and scheduling, which may reduce access and

adherence to exercise programs.

Digital health solutions, including telehealth and mobile health (mHealth) applications, have emerged to address these challenges in musculoskeletal care. Such interventions can deliver exercise instructions and monitoring remotely, potentially increasing access, engagement, and adherence while reducing costs. A recent meta-analysis of 56 randomized trials found that digital health interventions for musculoskeletal pain conditions produce small but statistically significant improvements in pain and function[3]. Moderate-quality evidence supports the conclusion that these digital interventions can reduce pain and improve disability and quality of life compared to usual care[3]. In the context of rehabilitation, multiple systematic reviews have noted that telehealth-delivered therapy shows benefits for chronic musculoskeletal pain conditions in general[4].

With respect to shoulder disorders specifically, early research suggests that remote therapies can be as effective as conventional care. For example, a systematic review of telerehabilitation for shoulder pain found very low to low-quality evidence that outcomes do not differ significantly between telerehabilitation and in-person physical therapy[5]. A more recent meta-analysis focusing on shoulder disorders reported that a 12-week telerehabilitation program led to superior improvements in range of motion, shoulder function, and quality of life compared to unsupervised home exercise, and that pain relief was greater when the program was sustained for over 12 weeks[6]. Likewise, a randomized controlled trial comparing a fully remote digital rehabilitation program to traditional high-intensity in-person therapy in chronic shoulder pain found no significant difference in functional outcomes between groups[7]. In that study, both digital and conventional groups achieved large improvements, demonstrating that a remote, app-based exercise program could match the effectiveness of clinic-based therapy[7]. These findings suggest that interactive home-based digital rehabilitation, especially when combined with therapist guidance, may achieve outcomes comparable to face-to-face physiotherapy in shoulder conditions.

Given these developments, we conducted a randomized controlled trial to evaluate a home-based generated physiotherapy program for patients with shoulder impingement. In the experimental group, a mobile app delivered a 12-week shoulder exercise regimen, featuring guided instructions, real-time feedback, and weekly live video sessions with a physiotherapist. The control group received 12 weeks of standard clinic-based face-to-face rehabilitation by a physical therapist. The purpose of the study was to evaluated the efficiency as well as cost-effectiveness of the digital system for shoulder impingement with compare to traditional in-person rehabilitation.

Methods

Study design and setting

In accordance with CONSORT guidelines[8], this single-center, prospective, parallel-group randomized controlled trial was conducted at the National Orthopaedics Center of China in Shanghai. The trial was preregistered with the Chinese Clinical Trial Registry (ChiCTR2100042097; registration date January 13, 2021) before patient enrollment. Patients were recruited between June 2021 and June 2024. Ethical approval was obtained from the Ethics Committee of Shanghai Sixth People's Hospital (approval No. 2019-KY-063(K)), and all participants provided written informed consent.

Participants

Potential participants were identified at the study's outpatient clinics and screened by the research team. Initial eligibility screening was performed by research staff, followed by a brief clinical interview by a study physician to confirm final eligibility. In accordance with CONSORT guidelines, all enrolled patients met predefined inclusion and exclusion criteria. These eligible criteria was shown in Table 1.

Intervention

Participants in the digital therapy (DT) group received a 12-week home-based exercise program delivered via a smartphone app (Joymotion®; Shanghai Medmotion Medical Management Co., Ltd., Shanghai, China). This app provided the Digital Physiotherapeutic Shoulder-Specific Training System, an evidence-based shoulder impingement protocol. It delivered guided exercise instructions and feedback on performance, and enabled real-time two-way video and audio interaction with the supervising physiotherapist. A technician installed the app on each patient's device on the day of hospital discharge, and patients used their home Wi-Fi to connect. The physiotherapist at the rehabilitation center scheduled one video-conference session per week for remote supervision. Each day, patients performed assigned exercises in the app (prescribed by the therapist to match the shared protocol), with detailed instructions and automatic tracking of completion. The app's program was tailored by the supervising physiotherapist to each patient but maintained parity with the PT group's exercise content. In sum, the DT group followed an individually adjusted shoulder exercise regimen with continuous tele-supervision .

In the clinic-based physiotherapy (PT) group, participants attended four supervised rehabilitation sessions per week for 12 weeks (with additional home exercises on non-clinic days). Each session was delivered face-to-face by an assigned physical therapist. Therapy components included manual

therapy (for example, glenohumeral joint mobilizations and soft-tissue mobilization to improve shoulder mobility and reduce pain) and supervised exercises targeting the rotator cuff and scapular stabilizers. Standard physiotherapy modalities were also applied as needed, for instance, therapeutic ultrasound was used for pain relief and function improvement. The content and progression of the exercise program in the PT group were matched to those of the DT group to ensure comparability. Home exercise assignments were given for days without clinic visits. Thus, both groups performed the same overall shoulder impingement rehabilitation protocol, with the DT group receiving it through app-based tele-rehabilitation and the PT group receiving in-person therapy (manual techniques, exercise and modalities).

The training protocol and the regulation protocol for this study was shown in Supplementary Materials.

Outcomes and Data Collection

The primary outcome is shoulder pain at rest, measured on a 0 to 100 Visual Analogue Scale (VAS) where 0 represents no pain and 100 represents worst pain. Secondary outcomes include shoulder pain during arm activity (measured by the VAS), shoulder function (Constant-Murley score), and health-related quality of life (SF-36 questionnaire and all eight of its domains: physical functioning, role limitations due to physical problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health)[9-12]. Patients' satisfaction with the intervention is also assessed using an online questionnaire of four items (convenience, ease of use and access, helpfulness, and communication), each rated on a 1 to 5 Likert scale (1 worst, 5 best).

Economic outcomes are also collected from a societal perspective. Total costs include direct medical costs, direct non-medical costs, and indirect costs (productivity costs, or opportunity costs)[13]. The inclusion of productivity costs reflects a societal perspective, in line with the China Guidelines for Pharmacoeconomic Evaluations (2020 Edition)[14]. To estimate intervention costs, we gathered data from the Hospital Information System (HIS) of Shanghai Jiao Tong University Affiliated Sixth People's Hospital and the online payment system of Shanghai Medmotion Medical Management Company.

Additional healthcare costs included expenses related to primary care (e.g., general practitioner visits), secondary care (e.g., follow-up hospital visits), and both prescribed and over-the-counter medications, all of which were obtained from the HIS.

Paid home care costs were evaluated by asking participants to report the hours of paid assistance they received, which were recorded during follow-ups at weeks. Informal care costs were also collected

during outpatient visits, based on the total hours patients received support from family, friends, and volunteers, with costs calculated by multiplying the total hours by the average hourly income in Shanghai.

For absenteeism and presenteeism costs, we employed the Productivity Cost Questionnaire[13]. We assessed sickness absence days using the Friction Cost Approach (FCA), with a friction period of 12 weeks and gender-specific price weights[13]. For presenteeism costs, participants reported the total number of days worked while experiencing health issues and their performance levels on a scale from 0 (unable to do anything) to 10 (able to do everything). The formula used to calculate presenteeism days was: Presenteeism days = ((10 - performance level) / 10) * number of days with health complaints, valued with gender-specific price weights.

To estimate unpaid productivity costs, we asked participants about the total hours they could not engage in unpaid tasks (e.g., chores, volunteer work, educational activities), which were valued based on the average hourly income in Shanghai.

Primary and secondary outcomes are assessed at 4, 12, and 24 weeks after randomization. Follow-up assessments are conducted in person in a dedicated outpatient clinic room by two trained physiotherapists who are blinded to group allocation. These assessors administer the VAS and Constant-Murley evaluations and oversee completion of the SF-36 and patient questionnaire at each visit.

Participants’ adherence and was measured using several indicators: the DT group participants' reported completion of sessions, average daily usage time, and weekly assessment completions, and the attendance rate of PT group participants at sessions[15]. Additionally, both groups rated their agreement with statements concerning adherence and acceptability on a scale from 0 ('strongly disagree') to 10 ('strongly agree'). Participants also provided qualitative assessments of their perceptions of the exercise protocol's outcomes[15].

Sample Size Calculation

The sample size was calculated to ensure adequate power to detect a non-inferiority margin based on the primary outcome’s minimal clinically important difference (MCID)[14]. In the context of postoperative pain, a change of approximately 10 mm on the 0–100 mm Visual Analog Scale (equivalent to 1.0 on a 0–10 scale) has been identified as a clinically meaningful difference. Thus, we set the non-inferiority margin equal to 1.0 VAS units. We assumed a standard deviation of about 2.0 units for VAS at rest based on similar analgesic studies and prior trials, reflecting moderate variability in pain scores. Using a two-sample t-test framework with 80 % power and a 5 %

significance level, and targeting a difference of 1.0 VAS units, the required sample size was calculated. Under these assumptions, approximately 50 patients per group (100 total) are needed to demonstrate that the new treatment is not worse than the control by more than 1.0 units on the VAS. Allowing for an estimated 25 % loss to follow-up, we would recruit about 66 patients per group (132 total) to maintain the desired power.

Randomization, Allocation and Blinding

Randomization was implemented using a blocked scheme to ensure balanced group sizes: specifically, a computer-generated sequence with randomly permuted blocks of 4–6 participants was prepared. The allocation sequence was generated by an independent statistician not otherwise involved in participant enrollment or assessment, to prevent predictability. Assignments were placed in sequentially numbered, sealed opaque envelopes prepared by the statistician to conceal the allocation order. Study investigators (who enrolled participants) assigned interventions by opening each envelope in order at the time of enrollment, thereby implementing the pre-generated sequence. Participants and study staff were not blinded to allocation; only the outcome assessors remained blinded to allocation throughout the trial.

Statistical analysis

Baseline characteristics, outcome measures, and treatment adherence were summarized using descriptive statistics. Continuous variables are presented as the mean plus or minus one standard deviation, and categorical data as counts and percentages. Results at each time point are reported in this way, and between-group differences are given as estimated coefficients with two-sided 95 percent confidence intervals. All statistical tests were two-sided with a 5 percent significance threshold.

The primary outcome (VAS score at 24 weeks) was tested for non-inferiority in the intention-to-treat population using a one-sided test at the 5 percent level. Missing outcome data were handled by multiple imputation[16]. In other words, plausible values were imputed for missing VAS scores and the non-inferiority hypothesis (that the new treatment is not worse than control by more than the prespecified margin) was evaluated accordingly.

VAS scores over time were compared between treatment groups using a linear mixed-effects regression model[17]. In this model the VAS score was the dependent variable. Fixed effects included treatment group, assessment time point, and covariates of interest (age, gender, and baseline VAS score). To account for the correlation of repeated measurements within participants, random

intercepts were included for each participant. A treatment-by-time interaction term was added so that the model could estimate how the difference between groups evolved across visits.

An analogous analysis was conducted in the per-protocol population, which was defined as the subset of participants who completed at least 80 percent of the required intervention sessions and had complete follow-up at all scheduled time points. Secondary outcomes were analyzed with similar mixed-effects models. To control the overall Type I error rate for multiple comparisons of secondary outcomes, a Bonferroni adjustment was applied[18].

The incremental cost-effectiveness ratio (ICER) was used to assess the cost-effectiveness of DT group compared with PT group. The ICER is the differential costs and outcomes between the DT group and the PT group. The numerator in the cost-effectiveness ratio is the monetary cost of the DT intervention minus the monetary cost of PT. The annual costs of the projects were calculated by converting the 12-week costs, the period used for implementation. The denominator is the score of outcomes gained by DT minus the score of outcomes gained by PT at 12 weeks.

We performed 1,000 bootstrapping iterations on our dataset[14]. For each iteration, we randomly sampled with replacement all patients from the DT group and PT group from the multiple imputed dataset. For each bootstrap sample, we calculated: the incremental cost between the two groups (using the 12-week cost data, which we treated as the total cost for the entire period) and the nine incremental effectiveness measures (three outcome measures at three time points). These incremental effectiveness values were derived from the coefficients of the interaction terms in the adjusted linear mixed-effects models described above. Based on these 1,000 bootstrap replicates, we constructed 95% confidence intervals (CIs) for all ICERs by extracting the 2.5th and 97.5th percentiles.

All statistical analyses were performed using R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

Results

Participants

Totally 282 participants were screened for eligibility and 220 participants were enrolled for randomization with 112 in DT group and 108 in PT group. The flow chart of the study was shown in Table 1. In the ITT population, baseline characteristics were generally similar between groups. Mean age was 50 (6.82) vs 51 (7.80) years (P=0.658); male patients 30.36% vs 36.11% (P=0.365); BMI 22 (2.14) vs 22 (1.88) kg/m2 (P=0.213). The dominant hand was affected in 73.21% vs 71.30% (P=0.751); duration of symptoms 22 (8.93) vs 21 (9.83) months (P=0.455). Able to work normally was reported by 59.82% vs 44.44% (P=0.022). Baseline shoulder outcome scores were comparable:

VAS at rest 42 (10.94) vs 42 (9.46) (P=0.676); VAS on activity 72 (16.92) vs 72 (14.53) (P=0.859); Constant–Murley score 33 (13.42) vs 34 (14.85) (P=0.510). SF-36 subscale scores did not differ between groups (all P≥0.134). Per-protocol analyses (Supplementary Table 1) showed similar results to the ITT analysis.

Primary and Secondary Outcomes

For VAS at rest (primary outcome), mean changes from baseline in DT vs PT were –9.28 (12.52) vs –8.36 (10.96) at 4 weeks (P = 0.539); –18.44 (12.16) vs –17.90 (10.28) at 12 weeks (P = 0.659); and –25.97 (11.96) vs –23.91 (10.33) at 24 weeks (P = 0.812). VAS on arm activity changed by –4.74 (20.89) vs –3.88 (17.93) at 4 weeks (P = 0.679); –26.59 (19.96) vs –26.06 (17.32) at 12 weeks (P = 0.809); and –28.35 (20.68) vs –24.94 (19.61) at 24 weeks (P = 0.558). Constant–Murley improved by 6.54 (14.16) vs 4.53 (15.82) at 4 weeks (P = 0.764); 11.47 (13.89) vs 10.37 (14.64) at 12 weeks (P = 0.910); and 25.81 (14.88) vs 24.38 (15.00) at 24 weeks (P = 0.855) (Table 3,4).

For SF-36, the Physical Functioning subscale changed by 3.27 (10.54) vs 0.05 (10.42) at 4 weeks (P = 0.004); 5.87 (9.99) vs 4.85 (11.54) at 12 weeks (P = 0.005); and 6.29 (10.74) vs 6.58 (12.43) at 24 weeks (P = 0.006). The Role-Physical subscale changed by –1.68 (21.27) vs –1.47 (20.16) at 4 weeks (P = 0.570); –0.48 (16.33) vs 4.85 (19.55) at 12 weeks (P = 0.009); and 4.76 (17.71) vs 5.61 (17.78) at 24 weeks (P = 0.012). General Health changed by –0.34 (7.01) vs –0.83 (7.28) at 4 weeks (P = 0.412); 5.77 (7.78) vs –0.15 (6.83) at 12 weeks (P = 0.001); and 6.24 (7.36) vs 6.07 (7.37) at 24 weeks (P = 0.028). Other SF-36 domains (Vitality, Social Functioning, Role-Emotional and Mental Health) showed negligible between-group effects. Patient evaluations of the interventions were also similar: at 4 weeks convenience change was 0.01 (0.26) vs 0.01 (0.26) (P = 0.813); ease of use was 0.01 vs –0.01 (P = 0.540); and differences at 12 and 24 weeks remained trivial (Table 3,4). The sensitivity analysis using per-protocol population showed similar results (Supplementary Table 2,3)

Cost-effectiveness Analysis

In the ITT population, mean total cost per patient was 44306.69 CNY (SD 13880.22) in the DT group versus 54853.65 CNY (SD 15181.20) in the PT group. The resulting incremental cost (DT vs PT) was -10546.96 CNY. Incremental cost-effectiveness ratios for outcomes were: VAS at rest: 92242.97 CNY; VAS on arm activity: 21552.47 CNY; Constant-Murley score: -107538.64 CNY. For SF-36 subscales, ICERs were -7353.25 CNY (Physical Functioning); 4826.18 CNY (Role-Physical); -169690.22 CNY (Bodily Pain); -12700.48 CNY (General Health); -16950.92 CNY (Vitality); -22336.64 CNY (Social Functioning); 11565.88 CNY (Role-Emotional); and -15260.98 CNY (Mental

Health). ICERs for patient experience questionnaires were: -3812797.34 CNY (Convenience); -2963794.75 CNY (Ease of use/access); 1549656.19 CNY (Helpfulness); and -3666339.90 CNY (Communication with care provider) (Table 5,6). The sensitivity analysis using per-protocol population showed similar results (Supplementary Table 4,5)

Adherence to treatment

Adherence outcomes (Table 7) showed similar session frequency: DT 5.17 (1.32) vs PT 5.15 (1.42) sessions/week (P = 0.848). The DT group's mean daily usage was 52.94 (5.92) minutes/day, with mean weekly assessment completions of 9.07 (2.02). Agreement scores for each question were high in both groups.

Discussion

In this study, the digital physiotherapeutic shoulder-specific training system produced clinical improvements that were broadly comparable to those achieved with conventional face-to-face physiotherapy. Both groups experienced similar reductions in pain and gains in shoulder function (the primary outcomes), with no meaningful differences between them, supporting our non-inferiority hypothesis. Secondary outcomes (such as health-related quality of life scores) also improved in both groups, and any between-group differences were small and inconsistent. Importantly, the digital intervention incurred lower overall costs while achieving comparable patient outcomes, indicating it was cost-effective relative to standard care. Overall, these findings suggest that the digital physiotherapy program is an effective and cost-saving alternative to conventional physiotherapy.

Recent randomized trials and meta-analyses indicate that home-based digital physiotherapy yields clinical outcomes (pain and function) that are comparable to those of traditional in-person care across a range of musculoskeletal disorders. For example, in chronic shoulder pain, a multicenter RCT found equivalent improvements in shoulder function (DASH scores) and high patient satisfaction in fully remote digital therapy versus high-intensity clinic-based rehabilitation[7]. Similarly, in knee osteoarthritis, tele-rehabilitation produced significant reductions in pain and gains in WOMAC function equivalent to those of conventional outpatient exercise programs[19]. In the postoperative setting, a trial of digitally-assisted home rehab after rotator-cuff repair found no difference in short-term recovery and even superior longer-term disability outcomes (QuickDASH and Constant-Murley scores) favoring the digital group[20]. At the systematic level, a 2025 meta-analysis of nonoperative shoulder conditions reported that 12-week telerehab protocols yielded modestly greater pain relief

(mean difference: –1.06 on a 0–10 scale) and small gains in range of motion compared to face-to-face care[21], though the evidence was graded low-certainty. Earlier syntheses have likewise concluded that real-time telerehabilitation is effective: for example, Cottrell et al. found that tele-therapy produced substantial functional gains (SMD 1.6 over controls) and was statistically equivalent to in-person physiotherapy for improving function and pain[22]. A broad meta-review of telerehabilitation across musculoskeletal conditions found overall that telerehab outperformed minimal or self-directed care, but performed similarly to standard physiotherapy[23]. Importantly, trials report high adherence and no excess harm with digital programs: dropout rates are low (completion 80–85% in both groups) and no study reported serious adverse events in the telehealth arms[7,23]. In one chronic shoulder study, both groups had high satisfaction, and no device-related injuries were observed[19]. The only noted differences were very small: for instance, a shoulder trial observed slightly greater average pain reduction and recommendation scores in the face-to-face group, but effect sizes were minimal and likely not clinically meaningful[7,23].

Evidence also favors the cost-effectiveness and patient acceptability of digital physiotherapy. A recent meta-analysis found that internet-based rehabilitation was on average modestly cheaper per patient than conventional therapy[23]. This is consistent with a large U.S. claims analysis, which showed that a digital-first musculoskeletal program was associated with over US$2,000 annual per-patient savings in overall MSK care costs (driven by reduced surgeries, imaging and clinic visits) compared to matched in-person PT cohorts[24]. Patients generally report high satisfaction with telerehabilitation; a systematic review concluded that satisfaction levels with digital delivery are comparable to face-to-face care, and in some studies even favored telehealth[25]. No specific harms of digital delivery have emerged beyond the usual technology and access limitations noted by authors. The main caveats are methodological: several reviews point out heterogeneity in study designs and some low-certainty evidence. For example, the shoulder telerehabilitation review flagged that most findings are low-certainty and called for more high-quality RCTs[21]. In summary, current high-quality evidence indicates that home-based digital physiotherapy for upper- and lower-limb conditions can achieve clinical outcomes on par with conventional therapy, while often reducing costs and being highly acceptable to patients[23,24]; to date, no safety concerns have been identified.

Musculoskeletal disorders impose an estimated 1.4% of global GDP loss[26], highlighting their societal impact. The study suggests integrating targeted exercise and rehabilitation strategies into routine clinical care and health planning. In China’s aging population, over 460 million people required rehabilitation in 2019[27], roughly one-third of the population. WHO notes that more than 50% of patients in low-income countries lack access to necessary rehabilitation services[28]. Implementing this

intervention could help fill these gaps, improve patient outcomes, and is likely cost effective in the long term. Health systems should incorporate such evidence-based programs into community and primary care to enhance equity and efficiency. These measures align with recommendations to strengthen prevention and rehabilitation infrastructure in developing regions[29,30], ultimately reducing disability and healthcare costs.

Our study has several strengthen: the trial's randomized, controlled design with prospective allocation maximizes internal validity and minimizes selection bias. It enrolled a moderate cohort and followed them over an eight- to twelve-week intervention period (with some studies reporting outcomes up to twelve months), which supports robustness of outcome assessment. The home-based digital system offered guided, feedback-supported exercises and achieved high adherence and patient satisfaction, consistent with evidence that digital support can improve short-term exercise adherence. Limitations include reduced external validity: the single-center, selected patient cohort and requirement for technology access may not generalize to all settings. Other concerns are unblinded participants (potential performance bias) and the usual RCT constraints: moderate size and short duration may limit detection of rare or long-term effects.

Conclusion

Both home-based digital training and conventional in-person physiotherapy led to similar improvements in shoulder function among patients with shoulder impingement. No significant difference was found in the primary outcome, and secondary outcomes (pain, satisfaction, adherence) were comparable between groups. These findings suggest that a home-based digital shoulder-specific training program may be a viable alternative to conventional physiotherapy in this patient population with cost-saving.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Shanghai Sixth People's Hospital (approval No. 2019-KY-063(K)). Written informed consent to participate was obtained from all individual participants.

Clinical trial number

The trial was preregistered with the Chinese Clinical Trial Registry (https://www.chictr.org.cn/, registration number: ChiCTR2100042097; registration date: January 13, 2021)

Consent for publication

All participants provided written consent for the publication of their anonymized data.

Competing interests

The authors declare that they have no competing interests.

Funding

This study received no specific funding.

Availability of data and materials

The datasets generated and analyzed during the current study are not publicly available. However, they are available from the corresponding author on reasonable request.

Authors' contributions

Conceptualization: Z.X. and S.L.

Methodology: Z.X. and S.L.

Formal Analysis: Z.L. and R.W.

Investigation: Z.L. and L.H.

Writing – Original Draft Preparation: Z.L.

Writing – Review & Editing: Z.X. and S.L.

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Figure Legends

Figure 1 shows the flow chart the study.

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Table 1 Eligible Criteria

Inclusion Criteria	Exclusion Criteria
1) Age 18 to 75 years.	1) Imaging evidence of full thickness tear, labral tear requiring surgery, or severe glenohumeral osteoarthritis excluded to avoid surgical pathologies
2) Clinical diagnosis of rotator cuff–related shoulder pain on history and examination. Pain located to the anterolateral shoulder, worse with overhead or loaded elevation and often disturbing sleep, with reproduction of symptoms on active and resisted movement, consistent with expert consensus descriptors.	2) Marked global restriction consistent with frozen shoulder or clinical instability signs excluded due to distinct management pathways.
3) At least two of the following were required on the affected side: Hawkins Kennedy sign, Neer sign, painful arc during abduction, resisted external rotation pain or weakness, or Jobe empty can pain or weakness. This cluster increases post test probability for subacromial pathology and rotator cuff disease compared with single tests.	3) Shoulder fracture, dislocation, or high energy injury to the affected shoulder within the prior 6 months excluded to avoid post traumatic courses.
4) Persistent symptoms beyond 3 months are typical of participants included in high quality trials and reduce spontaneous recovery confounding.	4) Cervical radiculopathy, peripheral neuropathy affecting the shoulder girdle, or thoracic outlet type referred pain excluded to reduce diagnostic heterogeneity.
5) Shoulder ultrasound or magnetic resonance imaging within 3 months of screening demonstrating tendinopathy or subacromial bursitis or partial thickness tendon involvement, and absence of full thickness rotator cuff tear. This mirrors the approach used in pivotal surgical and exercise trials that verified an intact cuff to avoid surgical tear indications.	5) Active inflammatory arthritis, uncontrolled metabolic or systemic illness that could confound outcomes excluded per guidance.
6) Average movement evoked pain of at least 3 of 10 on a numeric rating scale within the prior week and patient reported disability indicating at least mild functional limitation on SPADI or QuickDASH, reflecting outcome domains recommended in guidance.	6) Corticosteroid injection to the affected shoulder within 6 months or planned injection during the treatment phase excluded to avoid confounding treatment effects, consistent with large pragmatic trials.
7) Ability to understand study instructions, perform home exercises safely, and complete electronic assessments.	7) Recent postoperative states or being scheduled or strongly considered for surgery excluded to maintain a nonoperative cohort.
8) Possession or provision of a smartphone or tablet with home internet and basic digital literacy sufficient for video visits and in app exercise guidance, reflecting inclusion approaches used in recent digital physical therapy trials.	8) Unstable cardiopulmonary disease or other conditions limiting tolerance to light to moderate exercise excluded for safety.
	9) Conditions that would impede engagement with exercise instruction or communication excluded.
	10) Lack of feasible access to a smartphone or tablet or home internet or

9) Participants provided consent prior to any trial procedures.	inability to use video communication excluded due to intervention requirements.

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Table 2 Baseline characteristics of the DT group and PT group (intention-to-treat population)

ITT	Characteristic	DT group (N=112)	PT group (N=108)	P value
Demographics	Age (yr)	50 (6.82)	51 (7.80)	0.658
	Male Patients (no. [%])	34 (30.36)	39 (36.11)	0.365
	Body mass index (kg/m^2)	22 (2.14)	22 (1.88)	0.213
	Dominant hand affected (no. [%])	82 (73.21)	77 (71.30)	0.751
	Duration of symptoms (months)	22 (8.93)	21 (9.83)	0.455
	Able to work normally regardless of shoulder symptoms (no. [%])	67 (59.82)	48 (44.44)	0.022
Function	Visual Analogue Scale (VAS) score, at rest, baseline	42 (10.94)	42 (9.46)	0.676
	Visual Analogue Scale (VAS) score, on arm activity, baseline	72 (16.92)	72 (14.53)	0.859
	Constant-Murley score	33 (13.42)	34 (14.85)	0.510
	SF-36 Physical Functioning	75 (7.64)	75 (7.59)	0.717
	SF-36 Role-Physical	77 (14.90)	77 (13.03)	0.780
	SF-36 Bodily Pain	75 (7.24)	74 (7.25)	0.162
	SF-36 General Health	75 (4.55)	76 (5.19)	0.295
	SF-36 Vitality	70 (7.47)	70 (9.33)	0.898
	SF-36 Social Functioning	73 (6.93)	71 (7.15)	0.134
	SF-36 Role-Emotional	64 (9.74)	64 (10.33)	0.753
	SF-36 Mental Health	76 (8.27)	75 (7.84)	0.273

ITT: intention-to-treat; DT: Digital Physiotherapeutic Shoulder Impingement-Specific Training System; PT: Conventional physiotherapist face-to-face training; SF-36: MOS 36-Item Short-Form Health Survey.

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Table 3 Changes in outcomes at weeks 4, 12 and 24 (intention-to-treat population)

Outcomes	**4-weeks**			**12-weeks**			**24-weeks**		
	DT group (N=112)	**PT group (N=108)**	**P value**	**DT group (N=112)**	**PT group (N=108)**	**P value**	**DT group (N=112)**	**PT group (N=108)**	**P value**
Visual Analogue Scale (VAS) score, at rest	-9.28 (12.52)	-8.36 (10.96)	0.578	-18.44 (12.16)	-17.90 (10.28)	0.737	-25.97 (11.96)	-23.91 (10.33)	0.193
Visual Analogue Scale (VAS) score, on arm activity	-4.74 (20.89)	-3.88 (17.93)	0.750	-26.59 (19.96)	-26.06 (17.32)	0.841	-28.35 (20.68)	-24.94 (19.61)	0.230
Constant-Murley score	6.54 (14.16)	4.53 (15.82)	0.338	11.47 (13.89)	10.37 (14.64)	0.585	25.81 (14.88)	24.38 (15.00)	0.497
SF-36 Physical Functioning	3.27 (10.54)	0.05 (10.42)	0.029	5.87 (9.99)	4.85 (11.54)	0.503	6.29 (10.74)	6.58 (12.43)	0.856
SF-36 Role-Physical	-1.68 (21.27)	-1.47 (20.16)	0.942	-0.48 (16.33)	4.85 (19.55)	0.036	4.76 (17.71)	5.61 (17.78)	0.733
SF-36 Bodily Pain	0.23 (8.73)	2.37 (10.37)	0.110	3.54 (9.73)	5.30 (10.23)	0.212	6.16 (11.00)	8.01 (11.08)	0.235
SF-36 General Health	-0.34 (7.01)	-0.83 (7.28)	0.618	5.77 (7.78)	-0.15 (6.83)	0.000	6.24 (7.36)	6.07 (7.37)	0.872
SF-36 Vitality	6.78 (11.21)	4.61 (11.81)	0.177	6.73 (11.06)	6.84 (12.04)	0.948	11.05 (10.28)	10.82 (11.90)	0.882
SF-36 Social Functioning	4.44 (8.74)	5.18 (8.99)	0.553	4.55 (9.02)	6.96 (10.40)	0.079	8.17 (9.16)	8.76 (9.07)	0.649
SF-36 Role-Emotional	2.92 (11.66)	3.65 (12.53)	0.668	6.13 (13.02)	8.19 (15.98)	0.313	7.95 (14.30)	10.89 (17.13)	0.185
SF-36 Mental Health	0.27 (11.19)	1.33 (10.88)	0.490	1.88 (10.76)	3.55 (11.43)	0.287	3.89 (12.03)	4.94 (11.19)	0.520
Patients' evaluation on current intervention*									
Convenience (1-5)	0.01 (0.26)	0.01 (0.26)	0.996	0.01 (0.26)	0.01 (0.27)	0.987	0.00 (0.24)	0.01 (0.23)	0.756
Ease of use/access (1-5)	0.01 (0.26)	-0.01 (0.26)	0.595	0.00 (0.24)	0.00 (0.25)	1.000	0.01 (0.26)	0.00 (0.25)	0.790

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Helpfulness (1-5)	0.01 (0.22)	0.00 (0.20)	0.743	0.00 (0.28)	0.00 (0.25)	1.000	0.00 (0.24)	-0.01 (0.23)	0.756
Communication with the care provider (1-5)	0.00 (0.20)	0.015 (0.22)	0.738	0.00 (0.24)	0.00 (0.25)	1.000	0.01 (0.17)	-0.01 (0.23)	0.482

DT: Digital Physiotherapeutic Shoulder Impingement-Specific Training System; PT: Conventional physiotherapist face-to-face training; SF-36: MOS 36-Item Short-Form Health Survey.

*Patients' evaluation was collected by online questionnaire, the questionnaire has four questions concerning the convenience, ease of use/access, helpfulness, and the communication with the care provider, each question using a Likert of 1-5 points, in which 1 refer to the worst and 5 refer to best.

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Table 4 Effectiveness estimates from linear mixed effects models (intention-to-treat population)

Outcomes	4-weeks			12-weeks			24-weeks		
	Coefficient	95% CI	P value	Coefficient	95% CI	P value	Coefficient	95% CI	P value
Visual Analogue Scale (VAS) score, at rest	0.465	(-1.020, 1.951)	0.539	0.255	(-0.877, 1.386)	0.659	-0.114	(-1.055, 0.826)	0.812
Visual Analogue Scale (VAS) score, on arm activity	0.512	(-1.911, 2.935)	0.679	0.229	(-1.627, 2.084)	0.809	-0.489	(-2.127, 1.148)	0.558
Constant-Murley score	-0.297	(-2.231, 1.638)	0.764	-0.078	(-1.426, 1.270)	0.910	0.098	(-0.956, 1.152)	0.855
SF-36 Physical Functioning	2.157	(0.706, 3.608)	0.004	1.763	(0.520, 3.007)	0.005	1.434	(0.413, 2.456)	0.006
SF-36 Role-Physical	-0.726	(-3.231, 1.778)	0.570	-2.503	(-4.385, -0.621)	0.009	-2.185	(-3.881, -0.490)	0.012
SF-36 Bodily Pain	0.297	(-1.137, 1.731)	0.685	0.112	(-1.080, 1.304)	0.854	0.062	(-0.897, 1.021)	0.899
SF-36 General Health	-0.408	(-1.382, 0.566)	0.412	1.396	(0.551, 2.241)	0.001	0.830	(0.087, 1.573)	0.028
SF-36 Vitality	0.903	(-0.520, 2.325)	0.213	0.603	(-0.649, 1.854)	0.345	0.622	(-0.461, 1.705)	0.260
SF-36 Social Functioning	1.042	(-0.227, 2.312)	0.107	0.503	(-0.493, 1.499)	0.322	0.472	(-0.389, 1.334)	0.283

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SF-36 Role-Emotional	-0.029	(-1.644, 1.586)	0.972	-0.591	(-2.058, 0.876)	0.430	-0.912	(-2.336, 0.512)	0.209
SF-36 Mental Health	0.753	(-0.756, 2.262)	0.328	0.562	(-0.668, 1.792)	0.371	0.691	(-0.440, 1.822)	0.231
Patients' evaluation on current intervention*									
Convenience (1-5)	0.004	(-0.029, 0.037)	0.813	0.002	(-0.025, 0.029)	0.862	0.003	(-0.022, 0.027)	0.824
Ease of use/access (1-5)	0.012	(-0.025, 0.049)	0.540	0.006	(-0.025, 0.038)	0.698	0.004	(-0.024, 0.031)	0.798
Helpfulness (1-5)	-0.013	(-0.048, 0.022)	0.479	-0.010	(-0.037, 0.018)	0.504	-0.007	(-0.032, 0.018)	0.591
Communication with the care provider (1-5)	0.000	(-0.032, 0.032)	0.991	-0.002	(-0.029, 0.025)	0.890	0.003	(-0.021, 0.027)	0.817

DT: Digital Physiotherapeutic Shoulder Impingement-Specific Training System; PT: Conventional physiotherapist face-to-face training; SF-36: MOS 36-Item Short-Form Health Survey.

*Patients' evaluation was collected by online questionnaire, the questionnaire has four questions concerning the convenience, ease of use/access, helpfulness, and the communication with the care provider, each question using a Likert of 1-5 points, in which 1 refer to the worst and 5 refer to best.

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Table 5 Average total cost per patient (intention-to-treat population)

Cost category (CNY)	DT group (N=112)	PT group (N=108)	P value
Rehabilitation cost	6980.00 (0.00)	10904.52 (1487.27)	0.000
Primary care cost	123.56 (50.70)	1940.31 (264.64)	0.000
Secondary care cost	2571.96 (2698.84)	2973.64 (3480.57)	0.000
Paid home cost	238.29 (312.82)	408.55 (468.76)	0.359
Medication	5230.77 (1570.76)	7040.92 (1473.01)	0.003
Transportation cost	494.27 (173.20)	1493.51 (300.14)	0.000
Nutrition cost	2064.26 (478.42)	2046.07 (515.49)	0.000
Lost wages for patients	24103.96 (13233.95)	25250.79 (14510.13)	0.795
Lost wages for families	2499.63 (3519.43)	2795.34 (3691.82)	0.558
TOTAL COST	44306.69 (13880.22)	54853.65 (15181.20)	0.561

CNY: Chinese Yuan; DT: Digital Physiotherapeutic Shoulder Impingement-Specific Training System; PT: Conventional physiotherapist face-to-face training.

All relevant costs were captured from a societal perspective. This included direct medical costs (rehabilitation and physical therapy costs, outpatient visits and follow-up care, and medication costs), direct non-medical costs related to care (transportation for medical visits and any specialized nutritional support during recovery), and indirect costs due to productivity loss (lost wages for patients during recovery or disability, and lost income for family members/caregivers, if applicable). Costs were obtained from hospital billing records and patient self-reports where needed (wage losses). All costs are reported in 2024 Chinese Yuan, as 2024 was the end of the enrollment period; costs incurred in earlier years were adjusted to 2024 price levels using the consumer price index. Costs and outcomes occurring beyond the initial year were discounted at an annual rate of 3% to reflect time preference, consistent with standard practice in health economic evaluations.

Table 6 Incremental cost-effectiveness ratio (intention-to-treat population)

ITT	**Main analysis**
Incremental cost, CNY	-10546.96
Incremental Visual Analogue Scale (VAS) score, at rest	-0.114 (-1.055, 0.826)
Incremental Visual Analogue Scale (VAS) score, on arm activity	-0.489 (-2.127, 1.148)
Incremental Constant-Murley score	0.098 (-0.956, 1.152)
Incremental SF-36 Physical Functioning	1.434 (0.413, 2.456)
Incremental SF-36 Role-Physical	-2.185 (-3.881, -0.490)
Incremental SF-36 Bodily Pain	0.062 (-0.897, 1.021)
Incremental SF-36 General Health	0.830 (0.087, 1.573)
Incremental SF-36 Vitality	0.622 (-0.461, 1.705)
Incremental SF-36 Social Functioning	0.472 (-0.389, 1.334)
Incremental SF-36 Role-Emotional	-0.912 (-2.336, 0.512)
Incremental SF-36 Mental Health	0.691 (-0.440, 1.822)
Incremental Convenience (1-5)	0.003 (-0.022, 0.027)
Incremental Ease of use/access (1-5)	0.004 (-0.024, 0.031)
Incremental Helpfulness (1-5)	-0.007 (-0.032, 0.018)
Incremental Communication with the care provider (1-5)	0.003 (-0.021, 0.027)
ICER	
Visual Analogue Scale (VAS) score, at rest	92242.97
Visual Analogue Scale (VAS) score, on arm activity	21552.47
Constant-Murley score	-107538.64
SF-36 Physical Functioning	-7353.25
SF-36 Role-Physical	4826.18
SF-36 Bodily Pain	-169690.22
SF-36 General Health	-12700.48
SF-36 Vitality	-16950.92
SF-36 Social Functioning	-22336.64
SF-36 Role-Emotional	11565.88
SF-36 Mental Health	-15260.98
Convenience (1-5)	-3812797.34
Ease of use/access (1-5)	-2963794.75
Helpfulness (1-5)	1549656.19
Communication with the care provider (1-5)	-3666339.90

ITT: intention-to-treat; CNY: Chinese Yuan; SF-36: MOS 36-Item Short-Form Health Survey; ICER: Incremental cost-effectiveness ratio

Table 7 Patients' adherence to treatment (intention-to-treat population)

Outcome measure	**DT group (N=112)**	**PT group (N=108)**	**P value**
Number of sessions performed per week, mean (SD)	5.17 (1.32)	5.15 (1.42)	0.848
Average daily usage time (minutes), mean (SD)	52.94 (5.92)	/	/
Weekly assessment completions, mean (SD)	9.07 (2.02)	/	/
Agreement with the following questions (0 to 10)*, mean (SD)			
To what extent did you agree to accept the allocated exercise plan?	8.34 (1.32)	8.58 (1.24)	0.048
To what extent did you do the exercise program as recommended?	8.61 (1.41)	8.71 (1.43)	0.562
To what extent do you agree that the intervention relieved your pain?	8.69 (1.35)	8.79 (1.32)	0.343
To what extent do you agree that the intervention improved your function?	8.86 (1.21)	9.01 (1.11)	0.098
To what extent were you satisfied with the exercise protocol?	9.47 (0.51)	9.65 (0.52)	0.002

N/A, not applicable.

* 0 = strongly disagree, 10 = strongly agree.

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Supplementary Files

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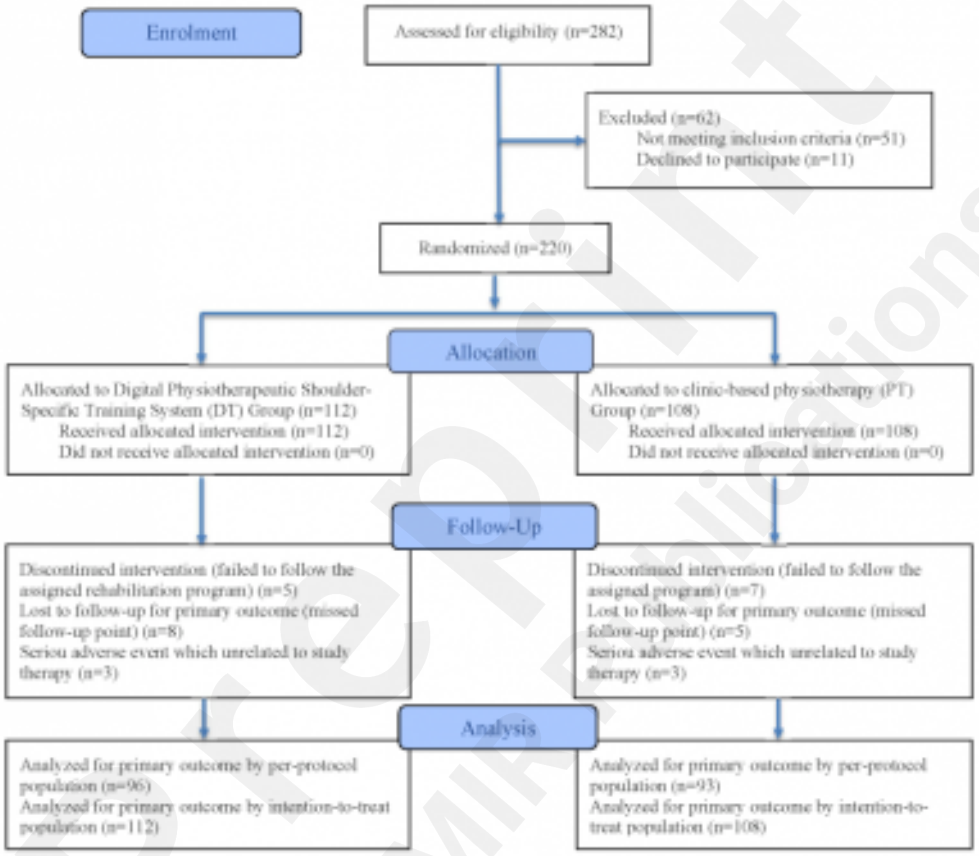
Figures

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This picture shows the flow diagram of the trial.

Figure 1: CONSORT 2025 Flow Diagram of the study

Flow diagram of the progress through the phases of a randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis)



Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123

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