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ORIGINAL ARTICLE OPEN ACCESS

Dose–Response Effects of a 4-Month FIT FIRST 10 School-Based Multisport Programme on Physical Fitness and Psychosocial Well-Being in Children Aged 7–11: A Three-Arm Cluster-Randomized Controlled Trial

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ABSTRACT

Low physical activity (PA) and fitness in childhood are linked to adverse health outcomes, yet many Danish children do not meet national guidelines. The FIT FIRST 10 (FF10) multisport PE programme was developed to increase PA in primary schools. To evaluate dose–response effects of a 4-month FF10 intervention on physical fitness and psychosocial well-being. Three-arm, cluster-randomized trial (1:1:1). 1357 pupils (7–11 years) from 68 classes in 27 schools were allocated to control (CON, $n = 529$), 1.5 FF10 sessions/week (1.5INT, $n = 495$), or 3 FF10 sessions/week (3INT, $n = 333$); 1175 provided consent. The primary outcome was cardiorespiratory fitness via the Yo-Yo Intermittent Recovery Level 1 Children's test (YYIR1C). Secondary outcomes included cardiometabolic health, muscular fitness, and psychosocial well-being. No between-group effects were observed for the primary outcome (1.5INT vs. CON: 17 m [−19, 52]; 3INT vs. CON: −8 m [−47, 31]). Among secondary outcomes, 1.5INT showed small favorable effects on body composition (body fat percentage −0.4%; fat mass −0.2 kg; fat mass index −0.1 kg/m²; BMI −0.1 kg/m²) and handgrip strength (+0.4 kg) (all $p < 0.05$). No intervention effects were observed for cardiovascular or psychosocial domains. Small differences favoring CON over 3INT emerged in standing long jump (−5 cm), postural balance (−0.5 s) and perceived flexibility (−0.3 AU) (all $p < 0.05$). In conclusion, a moderate, feasible dose of approximately 1.5 FF10 sessions per week appeared more effective than a higher-frequency implementation, highlighting the importance of feasibility and implementation fidelity in real-world school settings. [ClinicalTrials.gov](https://doi.org/10.1111/sms.70311) (NCT06180772).

Abbreviations: 3INT, 3 FF10 sessions per week; 5INT, 1.5 FF10 sessions per week; AAT, Arrowhead Agility Test; BMI, body mass index; CON, control group; CONSORT, Consolidated Standards of Reporting Trials; DBP, diastolic blood pressure; FF10, FIT FIRST 10; FIT FIRST, Frequent Intense Training through Football Interval Running, and Strength Training; FMI, fat mass index; HIIT, high-intensity interval training; HRmax, maximum heart rate; HRQoL, health-related quality of life; ICC, intraclass correlation coefficient; KS-27, KIDSCREEN-27; MAP, mean arterial pressure; MVPA, moderate-to-vigorous physical activity; PA, physical activity; PE, physical education; PSI-VS-ID-R, Physical Self-Inventory, very short form for youth with intellectual disabilities-revised; RHR, resting heart rate; SBP, systolic blood pressure; SLJ, standing long jump; VPA, vigorous physical activity; YYIR1C, Yo-Yo Intermittent Recovery Level 1 Children's Test.

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1 | Introduction

Regular physical activity (PA) in children is associated with a wide range of health benefits, including higher health-related quality of life (HRQoL) [1]. Furthermore, a child's physical self-concept is a strong predictor of their PA participation, suggesting that enhancing this self-concept could be a strategic approach to boosting and sustaining activity levels [2]. Establishing healthy PA behaviors early in life is crucial, as these habits often persist into adulthood, making primary school an essential period for fostering long-term motivation and well-being [3]. Schools have the unique capacity to reach almost all children, including those with lower fitness levels or health challenges, making them ideal settings for promoting PA. However, physical education (PE) lessons must achieve an adequate level of vigorous intensity to yield meaningful fitness gains, which is not consistently achieved in typical delivery [4].

Meanwhile, low fitness and adiposity during childhood are associated with clustering of cardiovascular risk factors and later disease, underscoring the public health importance of effective interventions [5–7]. National Danish guidelines recommend at least 60 min/day of moderate-to-vigorous PA (MVPA), including ≥ 3 weekly sessions of 30 min vigorous PA (VPA) for 5–17-year-olds [8]. A recent national monitoring report shows that adherence to these guidelines declines markedly across late childhood. Among 7–10-year-olds, slightly more than half meet the recommended 60 min of daily MVPA, but compliance drops rapidly thereafter; by approximately 11 years of age, fewer than half of children still meet the guideline [9].

To address children's inactivity, various school-based PA programs have been implemented, with multiple systematic reviews and meta-analyses indicating improvements in PA participation and selected mental well-being outcomes (e.g., PA enjoyment) [10, 11]. However, in Denmark, few multisport, school-based interventions have been rigorously evaluated. To help fill this gap, we developed the FIT FIRST 10 programme (Frequent Intense Training through Football, Interval Running, and Strength Training; FF10), designed to increase PA among primary school children and support adherence to national PA recommendations [12].

FF10 consists of 40-min sessions aligned with the PE curriculum and draws on 10 different sports, adapted for schools to emphasize high intensity, enjoyment, and inclusivity [12]. This program innovatively rethinks traditional sports by modifying rules, formats, and team structures to ensure meaningful participation for all children, regardless of their skill level or background. The program combines three complementary training modalities: small-sided team sports, interval running, and strength training, targeting multiple dimensions of physical fitness and health within the limited time available in PE.

Small-sided team games were chosen for their ability to elicit high levels of aerobic and musculoskeletal loading while maintaining engagement. Activities like football, basketball, and unihockey not only enhance cardiovascular and muscular fitness [4], but also foster psychological and social benefits, such

as greater enjoyment and perceived cohesion compared to individual sports [13, 14]. Evidence from high-intensity interval training (HIIT) further supports vigorous, intermittent exercise formats over low-intensity activity for improving fitness and health markers in children and adolescents [15].

Together, these modalities are intended to increase children's engagement in PA and exposure to VPA, thereby enhancing physical fitness, health markers, and movement-related competencies. Through participation in team-based activities, these gains may contribute to higher perceived physical competence and social cohesion. Consistent with this rationale, previous FF10 trials and the related “11 for Health” concept have demonstrated improvements in fitness, health markers, and selected domains of health-related quality of life (HRQoL) in school-aged children [16–19].

Despite the positive outcomes associated with three weekly 40-min sessions, the dose–response relationship—particularly the minimum effective dose for younger children—remains unclear. Evidence is even thinner for psychosocial outcomes such as HRQoL and physical self-concept, which are vital for long-term well-being and sustained PA participation.

Scheduling constraints often hinder teachers' ability to implement high volumes of activity, making it critical to identify a feasible dose that still produces measurable benefits for broader adoption. Notably, most school-based PA trials utilize two-arm designs that compare a single intervention dose with usual practice. This approach restricts the capacity to evaluate dose–response relationships effectively or to pinpoint a minimum effective dose [10].

Thus, we conducted a 4-month study of the FF10 intervention among children aged 7–11 years, randomly assigning schools to one of three conditions: three FF10 sessions per week, 1.5 FF10 sessions per week, or usual PE. This design allows us to estimate the minimum effective dose for key health indicators and assess whether a moderate, implementable dose can provide benefits comparable to a higher-frequency schedule, accommodating typical school routines.

We hypothesized that both FF10 intervention arms will outperform usual PE, particularly in the primary outcome—cardiorespiratory fitness—while secondary outcomes (muscular fitness, cardiometabolic health, HRQoL, and physical self-concept) will show smaller effects. Given the likely constraints on the achieved dose from scheduling and delivery factors, we anticipate no meaningful difference between the two FF10 doses.

2 | Methods

2.1 | Trial Design

We conducted a three-arm, cluster-randomized, parallel-group superiority trial in Danish primary schools over 4 months, delivered in two cohorts (2023 and 2024) with identical procedures. Schools were allocated 1:1:1 to control (CON), 1.5 FF10 sessions/week (1.5INT), or 3 FF10 sessions/

week (3INT) using computer-generated block randomization in Excel, stratified by number of classes and the population size of the school's town.

To minimize contamination, we employed cluster randomization at the school level. However, some spillover effects cannot be entirely excluded. Since the FF10 materials were publicly available and the delivery was teacher-led, intervention elements may have been adopted or adapted beyond the assigned groups. This potential contamination reflects the pragmatic nature of the trial and the real-world conditions of schools.

The study was unblinded, and the allocation sequence was prepared by the study team. One team member (MNL) was responsible for enrolling schools and assigning groups according to the sequence. Recruitment and enrolment of schools were completed before allocation disclosure. After allocation, all eligible pupils were invited to participate, and parental consent was obtained thereafter. Reporting follows CONSORT 2025 guidelines, including the extension for cluster-randomized trials. The completed CONSORT checklist is provided in Appendix S1.

2.2 | Ethics Approvals and Consent

The Health Research Ethics Committee of the Region of Southern Denmark reviewed the study and granted a waiver (S-20222000-108, Denmark). Institutional approval was obtained from the Legal Services Department, University of Southern Denmark (11.806). The study adhered to the Declaration of Helsinki. Written informed consent was obtained from parents prior to inclusion of participants' data; the parent information sheet and consent form are provided in Appendix S6. In accordance with our data-management plan and Danish regulations (GDPR), identifiable information is stored securely; study data will be deleted or anonymised no later than 5 years after project completion (by 01-08-2032).

2.3 | Recruitment

Registration was open to all public and private schools, while special schools for pupils with special educational needs were excluded. Recruitment ran from October 2022 to December 2023. Invitations were disseminated via social media (e.g., LinkedIn), the Danish Sports Confederation (DIF) website, and direct email. Direct email invitations were initially sent to schools in the Region of Southern Denmark and the Capital Region, reflecting their proximity to the coordinating university, and were subsequently extended to schools in other regions until the recruitment target was reached. Recruitment was completed before schools in the North Denmark Region were contacted, which had been planned as the final region due to logistical considerations. A minimum recruitment target of 60 classes across 24 schools was achieved.

In total, 27 schools volunteered to participate, representing four of Denmark's five regions: Syddanmark, Sjælland, Fyn, and Midtjylland. To enhance representativeness, two schools from Lolland-Falster were recruited deliberately, as this region is characterized by predominantly rural settings. Twelve

schools completed baseline assessments in January–February 2023 and 15 in January–February 2024; follow-up assessments for each cohort were conducted in May–June of the same year. Immediately after completing baseline assessments, all participating schools within each cohort initiated the 4-month FF10 intervention and adhered to identical procedures. Follow-up assessments were scheduled approximately 4 months after the start of each school's intervention.

2.4 | Participants

Pupils were eligible if they belonged to a participating class at a randomized school; no prespecified individual exclusion criteria were applied. Written parental consent for data use was obtained after randomization. Analyses included only consented pupils who remained in their class for the full intervention period. Potential harms, defined as adverse physical, emotional, or social events during baseline or follow-up assessments, were monitored without a formal protocol at those time points; pupils who became distressed during testing were reassured and could pause or decline participation. To minimize social comparison, individual test results were not shown on test days.

2.5 | Intervention

FF10 is a school-based multisport PE programme for Danish primary schools that emphasizes high-intensity activity through structured 40-min sessions delivered up to three times per week [12]. The programme comprises 60 lesson plans co-developed by a research team at the University of Southern Denmark, the Danish Sports Confederation (DIF), Team Denmark, and ten national sports federations (badminton, basketball, American football, soccer, handball, judo, orienteering, rugby, taekwondo, volleyball). FF10 is designed to be deliverable by any member of school staff and to fit into the regular timetable. Sessions are designed to elicit high intensity (average $\geq 75\%$ of maximum heart rate (HRmax), with $\geq 10\%$ of time $> 90\%$ HRmax) through team-based, small-sided games involving sprinting, strength exercises, and bone-loading movements. FF10 sessions were integrated into the regular timetable (during PE or substituting other lessons). Schools allocated to 1.5INT implemented an average of 1.5 sessions/week. This was operationalized by asking teachers to deliver one FF10 session in 1 week, followed by two sessions the following week. Those allocated to 3INT delivered three sessions each week. The active control continued the standard PE curriculum (2×45 min/week). Teachers implementing FF10 completed weekly class logbooks to record delivered activities and assess fidelity. After the intervention, they received an online questionnaire on programme acceptability, appropriateness, feasibility, as well as the teachers' capabilities, opportunities, and motivation related to its implementation [20].

2.6 | Teacher Courses

Teachers from intervention schools attended a one-day, in-person training course led by the FIT FIRST project team, often with representatives from participating federations. The course included a theoretical introduction to FF10's evidence

base and core principles (high intensity, enjoyment, inclusivity), as well as two practical sessions in a sports hall where teachers experienced key activities and explored lesson plans. Group discussions covered contextual adaptation and implementation strategies (e.g., timetabling, facilities). Courses were held in local schools or sports facilities.

All teachers in participating intervention classes who were interested in FF10 were invited to attend the training. In practice, the intervention was delivered by one or two teachers per class, and training courses were organized for each school (sometimes with schools combined) to ensure that at least 1–2 teachers per intervention school were able to participate. Approximately 40 teachers delivered the intervention in total, and at least one trained teacher responsible for each intervention class completed the course prior to programme implementation. Teachers received manuals with lesson plans for all ten sports and an equipment package (cones, bibs, and balls).

2.7 | Testing Procedures

All assessments were conducted during regular school hours by trained university staff using standardized protocols and identical equipment at both timepoints. We administered a standardized warm-up before the physical tests (Appendix S2). The physical test battery assessed cardiorespiratory and muscular fitness and cardiometabolic health, which are established predictors of current and future health [5]. Outcomes were measured at baseline and end-of-study follow-up.

2.7.1 | Primary Outcome

2.7.1.1 | Cardiorespiratory Fitness. Cardiorespiratory fitness was assessed using the Yo-Yo Intermittent Recovery Level 1 Children's test (YYIR1C), which involves 16-m shuttle runs with increasing intensity and 10-s recovery intervals [21]. On the test day, pupils first completed two slow familiarization shuttles with adult guidance. During the initial test stages, an adult paced the children to an average level of 14.8, corresponding to 19 shuttle runs (608 m). The outcome was the total distance covered (m).

2.7.2 | Secondary Outcomes

2.7.2.1 | Cardiometabolic Health. Body mass (kg) and body fat percentage were measured with an InBody 270 multifrequency body composition analyzer (Biospace, San Diego, CA) [22]. From these, we derived fat mass (kg), fat mass index (FMI; kg/m²), body mass index (BMI; kg/m²), and skeletal muscle mass (absolute and relative). Pupils were weighed barefoot in light clothing. Height was measured to 0.1 cm with a Tanita Leicester portable stadiometer (Tanita, Amsterdam, the Netherlands).

Systolic and diastolic blood pressure (SBP, DBP; mmHg) and resting heart rate (RHR; bpm) were measured with an automatic monitor (M6 HEM-7223-E, Omron, Illinois, USA) on the left upper arm in a quiet room with an appropriately sized cuff.

After an 8-min supine rest, three readings were taken at 1-min intervals; additional readings were obtained if values appeared unrealistic. Mean arterial pressure (MAP) was calculated from SBP and DBP as $(1/3 \times \text{SBP}) + (2/3 \times \text{DBP})$.

2.7.3 | Muscular Fitness

Lower-body explosive strength was assessed with a paused standing long jump (SLJ; cm) performed barefoot or in sports shoes. Participants stood behind the line, flexed their knees to approximately 90°, and jumped while keeping their hands on their hips. A new attempt was allowed if they fell backwards or dropped their arms. Two valid trials were recorded, separated by a short rest; the best distance was used.

Change-of-direction speed was measured using the Arrowhead Agility Test (AAT; s); a three-cone "arrowhead" layout with a start/finish line [23]. Participants ran from the line to the middle cone, turned around the side cone, looped the far cone, and finished by crossing the line. Runs were repeated if a cone was knocked over or stepped on. Each participant completed two valid right-turn trials, separated by 3 min; the best time was used.

Maximal isometric strength of the dominant hand (handgrip strength; kg) was measured using a Smedley dynamometer (Scanditact). Pupils stood against a wall, elbows at 90°, the palm facing outward, and squeezed maximally for 5 s. The higher of the two trials was recorded.

Postural balance (s) was assessed using the Stork Balance Stand Test. Participants stood barefoot or in socks with hands on their hips, placed the non-supporting foot against the knee of the supporting leg, and raised the heel of the supporting leg. Three trials were completed on each leg; the longest time maintained on either leg was used.

2.8 | Psychosocial Well-Being

Participants completed a combined questionnaire battery assessing: (a) biographical information, (b) leisure-time sports participation, (c) HRQoL, and (d) physical self-concept. Short forms were chosen for age-appropriate comprehension. All questionnaires were completed individually with headphones; researchers assisted as needed. Higher scores indicate more favorable outcomes.

Health-related quality of life (HRQoL) was assessed using the validated KIDSCREEN-27 well-being questionnaire (KS-27), a 27-item measure covering Physical Well-being, Psychological Well-being, Autonomy and Parent relation, Social Support and Peers, and School Environment. Items are rated on a five-point Likert scale (e.g., "never" to "always") [24]. We used an age-adjusted, video-assisted Danish version for children aged 6–10 years [25]. Raw dimension scores were transformed into norm-based T-scores (mean = 50, standard deviation (SD) = 10) using European reference values [26]. Values beyond ± 3 SDs were excluded (Appendix S3); thus, the analyzed T-scores fell within the range of approximately 20–80.

Physical self-concept was assessed with the Physical Self-Inventory, very short form for youth with intellectual disabilities (PSI-VS-ID-R) [27]. This instrument was originally developed for adolescents with intellectual disabilities and was designed with simplified wording, reduced response burden, and visual support to accommodate lower cognitive and verbal demands than those required by standard self-concept measures. Such characteristics align with established methodological recommendations for questionnaire-based self-report in younger children, who are still developing reading proficiency, abstract reasoning, and sustained attention [28]. To further enhance comprehension, the response format includes verbal descriptors alongside a graphical scale, and all items are supported by pictograms [27]. These adaptations have been shown to improve response quality in children aged 7–11 years by reducing cognitive load and supporting understanding of response options [28]. Accordingly, the PSI-VS-ID-R was considered appropriate for use in the present sample.

The PSI-VS-ID-R also includes a global self-worth domain, reported here as a secondary psychosocial outcome. The instrument contains 18 items across nine domains: global self-worth, physical self-worth, physical strength, physical attractiveness, physical condition, sport competence, perceived flexibility, balance, and running speed. Items are rated on a six-point graphical scale ranging from “No, I totally disagree” (very unhappy face) to “Yes, I totally agree” (very happy face). Domain scores were calculated as the mean of item responses, yielding domain scores ranging from 1 to 6. To aid comprehension, the questionnaire was administered in a video- and smiley-assisted format, consistent with KS-27. The average of each domain was calculated; score range was from 1 to 6.

2.9 | Patient and Public Involvement

Results will be shared with participating schools by email and disseminated via seminars for relevant professionals and press releases targeting the public (e.g., parents).

2.10 | Sample Size

This pragmatic trial aimed to recruit approximately 1500 pupils across 60 classes from 24 schools (1:1:1). The target sample was determined by feasibility (recruitment, timetabling, staffing, and equipment) rather than a formal a priori power calculation. Consequently, inference emphasized estimation, and we report adjusted effect sizes with 95% confidence intervals (CIs).

2.11 | Statistical Analysis

Analyses were conducted in RStudio (v2025.05.1, Posit) using lme4/lmerTest [29]. Outlier handling is described in Appendix S3. Linear mixed models with Gaussian residuals were fitted to estimate intervention effects. Fixed effects were group (CON, 1.5INT, 3INT), time (baseline, follow-up), and their interaction, with prespecified covariates. For physical outcomes, models adjusted for sex (reference category: boys),

age, height, body mass, and baseline leisure-time sports participation; for psychosocial outcomes, height and body mass were omitted. Continuous covariates, including the numeric leisure-time sports participation variable, were mean-centred prior to analysis. Random intercepts for pupil (ID) and class accounted for repeated measures and clustering. Class-level intraclass correlation coefficients (ICCs) were estimated from the mixed-effects models.

The primary estimate was the between-group difference in change from baseline to follow-up (difference-in-differences). With treatment coding (CON and baseline as reference levels), interaction terms for 1.5INT \times follow-up and 3INT \times follow-up estimated changes relative to CON; the 3INT versus 1.5INT comparison was obtained by re-leveling Group. We report Wald estimates with 95% CIs and *p*-values from fixed-effect Wald tests with Satterthwaite degrees of freedom. Simple effects (within-group changes from baseline to follow-up) were obtained using estimated marginal means for each group and computing follow-up minus baseline contrasts. Analyses used all available observations from consented pupils who remained in their class; rows with missing model variables were excluded (observation-level complete case). We assumed data were missing at random; although missingness was somewhat higher in 3INT, it was similar across outcomes and models adjusted for key covariates.

No interim analyses or formal stopping rules were prespecified. Schools could pause or modify sessions for operational reasons (e.g., timetabling, staffing), independent of outcomes; such deviations were recorded. Analyses followed the intention-to-treat principle with participants analyzed as randomized. For continuous outcomes, we present means (SD) and adjusted between-group differences in change with 95% CIs. Statistical significance was set at $p < 0.05$.

Secondary outcome analyses were exploratory; adjustment for multiple comparisons was considered but not applied, as the primary outcome was prespecified and secondary analyses were intended to be hypothesis-generating. Findings should therefore be interpreted with caution.

3 | Results

3.1 | Participants

Twenty-seven schools (68 classes; 1357 pupils) were cluster-randomized (1:1:1). Parental consent was obtained for 1175 pupils. Primary analyses included consented pupils with valid outcome data; exclusions due to lack of consent, absence at testing, invalid measurements (e.g., comprehension error, injury, protocol deviations), or school transfer/enrolment only at follow-up are detailed in Figure 1. For the primary outcome, 1025 pupils had valid baseline measurements, and 875 pupils (CON $n = 350$; 1.5INT $n = 310$; 3INT $n = 215$) provided complete data at both baseline and follow-up. Lost to follow-up denotes pupils with baseline data but no follow-up measure.

Baseline characteristics are presented in Table 1. Based on teacher logbooks, the achieved dose averaged 1.8 ± 0.8 (1.5INT)

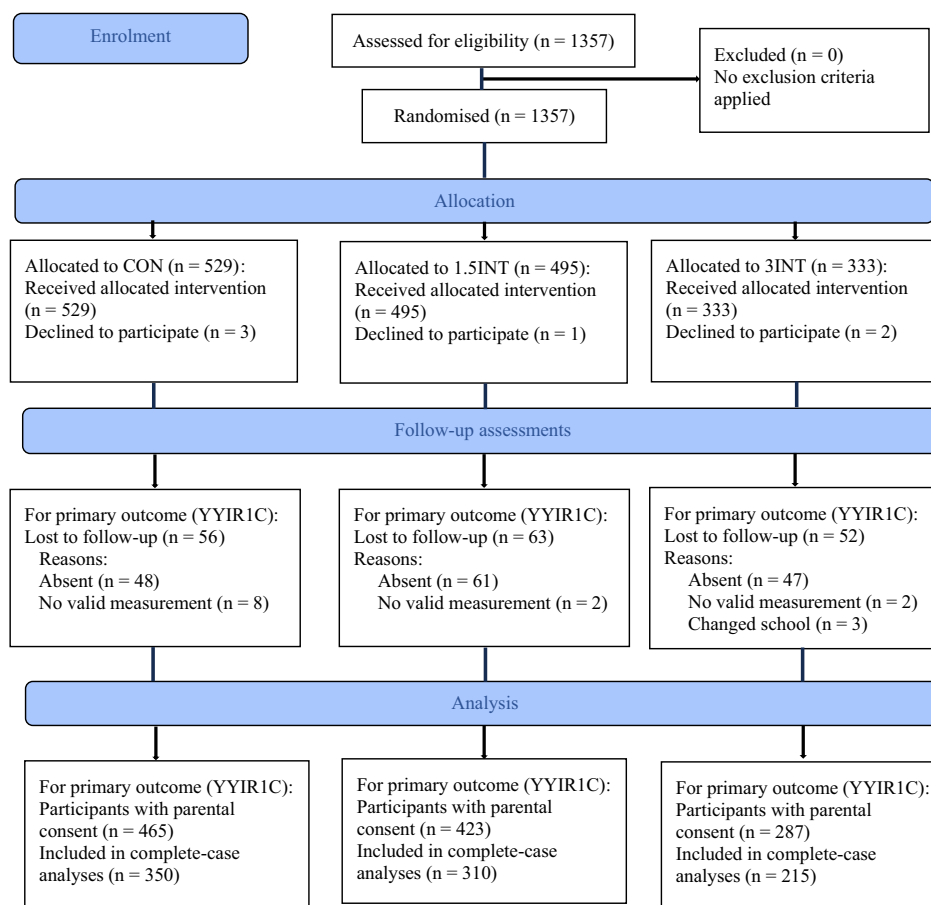


FIGURE 1 | CONSORT flow diagram. CON, control group; YYIR1C, Yo-Yo Intermittent Recovery Level 1 Children's Test; 1.5INT, 1.5 FF10 sessions/week; 3INT, 3 FF10 sessions/week.

TABLE 1 | Participant characteristics at baseline.

	CON	1.5INT	3INT
<i>Categorical variables</i>			
Number of participants (n)	465 (39.6%)	423 (36.0%)	287 (24.4%)
Sex, boys (n)	220 (47.3%)	206 (48.7%)	151 (52.6%)
Active in leisure-time sports, yes (n)	307 (70.3%)	277 (68.2%)	221 (81.5%)
<i>Numerical variables</i>			
Age (years)	8.6 (0.6) n = 416	8.7 (0.7) n = 386	8.5 (0.6) n = 264
Body mass (kg)	33.3 (7.4) n = 416	33.0 (7.7) n = 366	33.5 (8.2) n = 268
Height (cm)	137.8 (6.8) n = 418	137.2 (7.2) n = 366	137.7 (7.0) n = 267

Note: Numerical variables are presented as mean ± SD. Abbreviations: 1.5INT, 1.5 FF10 sessions/week; 3INT, 3 FF10 sessions/week; CON, control group.

and 2.2 ± 0.7 (3INT) FF10 sessions per week, delivered over a mean of 13.2 and 16.4 weeks, respectively. PE-trained teachers delivered FF10 in 47.4% of 1.5INT classes versus 38.5% of 3INT classes (the remainder were non-PE teachers). Teacher motivation scores were low in both intervention groups ($< 3.5/5$). Implementation, in addition to PE, occurred in 45.8% of 1.5INT

classes but only 10.5% of 3INT classes [20]. No serious adverse events were reported in any group during baseline or follow-up assessments.

Table 2 shows observed means, SDs, and sample sizes for each outcome at baseline and follow-up. Table 3 reports adjusted

TABLE 2 | Descriptives for outcome variables before (baseline) and after (follow-up) by group.

Outcome variables	CON		1.5INT		3INT	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
<i>Cardiorespiratory fitness</i>						
YYIRIC distance (m)	391 (283) n = 403	481 (339) n = 398	363 (287) n = 364	469 (332) n = 351	378 (266) n = 258	469 (323) n = 236
<i>Anthropometrics</i>						
Body mass (kg)	33.3 (7.4) n = 416	35.3 (8.3) n = 430	33.0 (7.7) n = 365	34.7 (8.2) n = 375	33.5 (8.2) n = 268	34.4 (8.1) n = 247
Height (cm)	137.8 (6.8) n = 418	140.0 (7.0) n = 431	137.2 (7.2) n = 366	139.7 (7.4) n = 375	137.7 (7.0) n = 267	139.6 (7.0) n = 247
<i>Cardiometabolic health</i>						
Body fat percentage (%)	22.0 (8.7) n = 410	22.2 (8.9) n = 427	22.0 (8.5) n = 360	21.8 (8.5) n = 370	20.9 (8.8) n = 267	20.3 (8.5) n = 247
Fat mass (kg)	7.8 (4.9) n = 410	8.4 (5.5) n = 427	7.8 (4.9) n = 360	8.1 (5.1) n = 369	7.6 (5.3) n = 267	7.5 (5.1) n = 247
FMI (kg/m ²)	4.1 (2.4) n = 410	4.2 (2.5) n = 427	4.1 (2.4) n = 358	4.1 (2.4) n = 368	3.9 (2.5) n = 265	3.8 (2.4) n = 247
BMI (kg/m ²)	17.4 (3.0) n = 415	17.9 (3.1) n = 430	17.4 (3.0) n = 366	17.6 (3.1) n = 374	17.5 (3.1) n = 266	17.5 (3.0) n = 247
SBP (mmHg)	96.7 (9.5) n = 407	95.6 (9.7) n = 417	96.5 (8.7) n = 356	96.2 (8.4) n = 368	95.8 (10.4) n = 266	95.3 (10.2) n = 240
DBP (mmHg)	69.3 (9.4) n = 408	66.0 (8.7) n = 418	68.1 (7.9) n = 356	66.0 (7.5) n = 368	67.7 (8.8) n = 267	66.0 (8.7) n = 240
MAP (mmHg)	78.3 (8.3) n = 407	75.8 (8.0) n = 417	77.6 (7.4) n = 356	76.1 (6.8) n = 368	77.0 (8.6) n = 266	75.8 (8.7) n = 240
RHR (bpm)	73.9 (11.7) n = 408	73.0 (10.3) n = 418	72.2 (11.3) n = 356	71.6 (10.6) n = 367	74.1 (10.5) n = 265	74.1 (10.5) n = 240
<i>Muscular fitness</i>						
SLJ performance (cm)	104 (19) n = 407	114 (19) n = 421	102 (18) n = 373	111 (18) n = 369	106 (17) n = 262	113 (16) n = 241
AAT performance (s)	11.7 (1.2) n = 405	11.3 (1.1) n = 417	11.8 (1.2) n = 357	11.3 (1.0) n = 356	11.7 (1.2) n = 234	11.1 (0.9) n = 211

(Continues)

TABLE 2 | (Continued)

Outcome variables	CON		1.5INT		3INT	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
Postural balance (s)	3.2 (2.7) n = 405	3.9 (3.4) n = 424	3.4 (2.5) n = 367	3.7 (2.3) n = 373	3.1 (3.1) n = 261	3.3 (1.7) n = 245
Handgrip strength (kg)	14.3 (3.4) n = 415	14.8 (3.6) n = 431	14.4 (3.6) n = 368	15.5 (4.4) n = 378	14.8 (3.3) n = 269	15.2 (3.6) n = 246
Muscle mass (kg)	13.1 (2.2) n = 412	13.9 (2.4) n = 426	13.0 (2.4) n = 365	13.8 (2.6) n = 375	13.4 (2.4) n = 268	13.9 (2.4) n = 241
Relative muscle mass (%)	40.0 (4.4) n = 412	40.1 (4.5) n = 426	39.9 (4.3) n = 365	40.2 (4.5) n = 374	40.6 (4.4) n = 268	41.1 (4.4) n = 241
<i>Psychosocial well-being</i>						
Physical Well-being (AU)	48.1 (8.1) n = 418	50.3 (8.8) n = 417	48.5 (9.8) n = 387	50.2 (8.7) n = 374	48.6 (8.2) n = 262	50.5 (8.3) n = 247
Psychological well-being (AU)	48.7 (8.3) n = 419	49.3 (9.0) n = 418	48.4 (8.8) n = 387	48.7 (8.5) n = 374	48.3 (8.2) n = 263	49.3 (8.2) n = 247
Autonomy and Parent relation (AU)	46.4 (7.2) n = 411	48.9 (9.2) n = 418	46.9 (7.4) n = 365	49.0 (9.3) n = 372	46.3 (6.9) n = 255	48.6 (8.6) n = 247
Social support and peers (AU)	50.1 (8.7) n = 417	51.1 (8.8) n = 418	50.2 (9.1) n = 379	50.5 (9.1) n = 373	49.7 (8.5) n = 261	50.0 (8.7) n = 245
School environment (AU)	52.6 (10.1) n = 417	52.4 (9.9) n = 417	52.1 (10.2) n = 381	51.6 (9.9) n = 374	51.1 (9.6) n = 260	51.3 (9.4) n = 245
Global self-worth (AU)	5.2 (1.0) n = 413	5.3 (1.0) n = 414	5.2 (0.9) n = 328	5.2 (1.1) n = 318	5.3 (1.0) n = 241	5.3 (0.9) n = 218
Physical self-worth (AU)	5.2 (1.0) n = 411	5.3 (0.9) n = 413	5.3 (1.0) n = 330	5.2 (1.0) n = 318	5.3 (0.8) n = 240	5.3 (0.9) n = 217
Physical strength (AU)	4.4 (1.1) n = 406	4.4 (1.1) n = 410	4.4 (1.2) n = 329	4.4 (1.1) n = 316	4.4 (1.0) n = 241	4.4 (1.0) n = 215
Physical attractiveness (AU)	4.3 (1.2) n = 394	4.4 (1.2) n = 396	4.3 (1.3) n = 264	4.3 (1.2) n = 238	4.2 (1.2) n = 233	4.4 (1.1) n = 203
Physical condition (AU)	4.0 (1.3) n = 414	4.2 (1.2) n = 417	4.0 (1.4) n = 333	4.1 (1.3) n = 319	4.3 (1.2) n = 243	4.3 (1.2) n = 219

(Continues)

TABLE 2 | (Continued)

Outcome variables	CON		1.5INT		3INT	
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up
Sport competence (AU)	4.4 (1.1) n = 408	4.4 (1.1) n = 414	4.3 (1.2) n = 331	4.3 (1.2) n = 318	4.4 (1.1) n = 242	4.5 (1.0) n = 218
Flexibility (AU)	4.3 (1.2) n = 355	4.5 (1.2) n = 372	4.2 (1.2) n = 289	4.3 (1.3) n = 275	4.5 (1.2) n = 213	4.4 (1.2) n = 193
Balance (AU)	4.3 (1.2) n = 412	4.4 (1.1) n = 414	4.3 (1.2) n = 326	4.3 (1.2) n = 317	4.4 (1.2) n = 241	4.3 (1.1) n = 217
Speed (AU)	4.8 (1.1) n = 414	4.7 (1.2) n = 416	4.7 (1.2) n = 330	4.6 (1.2) n = 317	4.9 (1.1) n = 241	4.7 (1.1) n = 218

Note: Mean (SD) and sample sizes for outcome variables before (baseline) and after (follow-up) the 4-month FF10 intervention for each of the three arms.

Abbreviations: 1.5INT, 1.5 FF10 sessions/week; 3INT, 3 FF10 sessions/week; AAT, Arrowhead Agility Test; BMI, body mass index; CON, control group; DBP, diastolic blood pressure; FMI, fat mass index; MAP, mean arterial blood pressure; RHR, resting heart rate; SBP, systolic blood pressure; SLJ, standing long jump; YYIR1C, Yo-Yo Intermittent Recovery Level 1 Children's Test.

between-group differences in change from baseline to follow-up from the mixed-effects models. Full model outputs and per-outcome class-level ICCs are provided in Appendix S4, and within-group (follow-up—baseline) changes for each outcome are presented in Appendix S5.

3.2 | Cardiorespiratory Fitness

All groups improved from baseline to follow-up in YYIR1C distance (all $p < 0.001$; Appendix S5); however, between-group differences in change were not significant: 1.5INT vs. CON, 17m [95% CI -19, 52]; $p = 0.350$; 3INT vs. CON, -8m [95% CI -47, 31]; $p = 0.679$; 3INT vs. 1.5INT, -25m [95% CI -65, 15]; $p = 0.221$ (Table 3). The class-level ICC was 0.10, indicating that approximately 10% of the variance in YYIR1C was attributable to differences between classes (Appendix S4).

3.3 | Cardiometabolic Health

The 1.5INT group showed more favorable changes in body composition than CON: greater reduction in body fat percentage (-0.4% [95% CI -0.8, 0.0]; $p = 0.029$), a smaller gain in fat mass (-0.2 kg [95% CI -0.3, 0.0]; $p = 0.021$), and more favorable changes in FMI (-0.1 kg/m² [95% CI -0.2, 0.0]; $p = 0.016$) and BMI (-0.1 kg/m² [95% CI -0.2, 0.0]; $p = 0.013$). The 3INT group generally did not differ from CON on these indices (Table 3). No significant between-group differences were observed for SBP, DBP, MAP, or RHR (Table 3).

3.4 | Muscular Fitness

In SLJ, all groups improved (all $p < 0.001$; Appendix S5), with 3INT improving less than CON (-5 cm [95% CI -7, -2]; $p < 0.001$) and 1.5INT (-3 cm [95% CI -5, -1]; $p = 0.010$; Table 3). In postural balance, both intervention groups showed smaller gains than CON (1.5INT: -0.6 s [95% CI -1.0, -0.2]; $p = 0.004$; 3INT: -0.5 s [95% CI -0.9, 0.0]; $p = 0.038$). Handgrip strength increased in all groups; 1.5INT improved more than CON (+0.4 kg [95% CI 0.0, 0.8]; $p = 0.046$), and 3INT improved less than 1.5INT (-0.5 kg [95% CI -0.9, 0.0]; $p = 0.048$). In AAT, absolute and relative muscle mass, all groups improved (all $p \leq 0.007$; Appendix S5), with no significant Time \times Group interactions (Table 3).

3.5 | Psychosocial Well-Being

Across KS-27 and the PSI-VS-ID-R domains, no significant between-group differences were observed, except for the flexibility domain, where 3INT scored lower than CON (-0.3 [95% CI -0.5, -0.1]; $p = 0.013$; Table 3).

4 | Discussion

The primary objective of this study was to examine the dose-response effects of a 4-month FF10 intervention on multiple fitness and health indicators in children aged 7–11 years. A

TABLE 3 | Adjusted between-group differences in change (follow-up—baseline).

Outcome variables	1.5INT vs. CON			3INT vs. CON			3INT vs. 1.5INT		
	Est.	95% CI	<i>p</i>	Est.	95% CI	<i>p</i>	Est.	95% CI	<i>p</i>
<i>Cardiorespiratory fitness</i>									
YYIR1C distance (m)	16.91	[-18.54, 52.40]	0.350	-8.22	[-47.20, 30.80]	0.679	-25.13	[-65.33, 15.10]	0.221
<i>Cardiometabolic health</i>									
Body fat percentage (%)	-0.42	[-0.79, -0.04]	0.029	-0.01	[-0.42, 0.40]	0.962	0.41	[-0.02, 0.83]	0.062
Fat mass (kg)	-0.19	[-0.35, -0.03]	0.021	-0.08	[-0.26, 0.09]	0.340	0.10	[-0.08, 0.28]	0.269
FMI (kg/m ²)	-0.10	[-0.18, -0.02]	0.016	-0.03	[-0.12, 0.06]	0.571	0.08	[-0.02, 0.17]	0.115
BMI (kg/m ²)	-0.12	[-0.21, -0.02]	0.013	-0.08	[-0.19, 0.02]	0.105	0.03	[-0.07, 0.14]	0.540
SBP (mmHg)	0.79	[-0.74, 2.31]	0.313	0.60	[-1.08, 2.28]	0.483	-0.18	[-1.92, 1.56]	0.836
DBP (mmHg)	1.01	[-0.62, 2.63]	0.224	1.52	[-0.27, 3.30]	0.095	0.51	[-1.34, 2.36]	0.588
MAP (mmHg)	0.91	[-0.51, 2.34]	0.209	1.20	[-0.37, 2.76]	0.134	0.28	[-1.34, 1.90]	0.732
RHR (bpm)	0.13	[-1.72, 1.97]	0.894	-1.68	[-3.72, 0.35]	0.105	-1.81	[-3.92, 0.30]	0.093
<i>Muscular fitness</i>									
SLJ performance (cm)	-1.71	[-3.73, 0.32]	0.099	-4.72	[-6.96, -2.49]	<0.001	-3.02	[-5.33, -0.71]	0.010
AAT performance (s)	-0.11	[-0.24, 0.02]	0.101	-0.05	[-0.20, 0.10]	0.517	0.06	[-0.09, 0.22]	0.438
Postural balance (s)	-0.57	[-0.96, -0.18]	0.004	-0.46	[-0.89, -0.03]	0.038	0.12	[-0.33, 0.56]	0.610
Handgrip strength (kg)	0.42	[0.01, 0.82]	0.046	-0.05	[-0.50, 0.40]	0.819	-0.47	[-0.93, 0.00]	0.048
Muscle mass (kg)	-0.02	[-0.11, 0.07]	0.673	-0.07	[-0.18, 0.03]	0.149	-0.05	[-0.16, 0.05]	0.308
Relative muscle mass (%)	0.20	[-0.05, 0.46]	0.123	0.02	[-0.26, 0.30]	0.888	-0.18	[-0.47, 0.11]	0.225
<i>Psychosocial well-being</i>									
Physical well-being (AU)	-0.54	[-1.87, 0.79]	0.426	-0.58	[-2.08, 0.92]	0.450	-0.04	[-1.56, 1.49]	0.962
Psychological well-being (AU)	0.08	[-1.06, 1.21]	0.895	0.48	[-0.79, 1.76]	0.457	0.41	[-0.89, 1.71]	0.538
Autonomy and parent relation (AU)	-0.16	[-1.29, 0.97]	0.782	-0.11	[-1.37, 1.16]	0.869	0.05	[-1.24, 1.35]	0.937
Social support and peers (AU)	-0.25	[-1.62, 1.13]	0.726	-0.52	[-2.06, 1.03]	0.512	-0.27	[-1.85, 1.31]	0.736
School environment (AU)	0.25	[-1.11, 1.62]	0.717	0.54	[-1.00, 2.08]	0.495	0.28	[-1.29, 1.85]	0.722
Global self-worth (AU)	-0.05	[-0.21, 0.10]	0.500	-0.04	[-0.21, 0.14]	0.680	0.02	[-0.16, 0.20]	0.852
Physical self-worth (AU)	-0.09	[-0.23, 0.05]	0.222	-0.12	[-0.27, 0.03]	0.127	-0.03	[-0.20, 0.13]	0.684
Physical strength (AU)	0.01	[-0.14, 0.16]	0.874	-0.10	[-0.26, 0.07]	0.263	-0.11	[-0.28, 0.07]	0.228
Physical attractiveness (AU)	-0.16	[-0.34, 0.02]	0.090	0.01	[-0.18, 0.21]	0.899	0.17	[-0.04, 0.38]	0.113
Physical condition (AU)	0.00	[-0.18, 0.18]	1.000	-0.17	[-0.37, 0.02]	0.082	-0.17	[-0.38, 0.03]	0.097
Sport competence (AU)	-0.01	[-0.18, 0.16]	0.893	0.11	[-0.08, 0.29]	0.254	0.12	[-0.07, 0.31]	0.228
Flexibility (AU)	-0.11	[-0.31, 0.09]	0.268	-0.28	[-0.50, -0.06]	0.013	-0.17	[-0.40, 0.06]	0.155
Balance (AU)	-0.06	[-0.24, 0.13]	0.563	-0.11	[-0.31, 0.10]	0.322	-0.05	[-0.27, 0.17]	0.656
Speed (AU)	0.03	[-0.12, 0.19]	0.658	-0.11	[-0.28, 0.06]	0.193	-0.15	[-0.32, 0.03]	0.105

Note: Estimates reflect between-group differences in change from baseline to follow-up. CON was the reference group for comparisons vs. 1.5INT and 3INT; 1.5INT was the reference for the 3INT vs. 1.5INT comparison. Positive values indicate greater changes in the first-mentioned group at follow-up than at baseline. Statistically significant *p*-values (<0.05) are shown in bold.

Abbreviations: 1.5INT, 1.5 FF10 sessions/week; 3INT, 3 FF10 sessions/week; AAT, Arrowhead Agility Test; BMI, body mass index; CON, control group; DBP, diastolic blood pressure; FMI, fat mass index; MAP, mean arterial blood pressure; RHR, resting heart rate; SBP, systolic blood pressure; SLJ, standing long jump; YYIR1C, Yo-Yo Intermittent Recovery Level 1 Children's Test.

moderate dose of 1.5 sessions/week produced small but favorable changes in body composition and handgrip strength. Delivering the FF10 programme with a higher frequency of three sessions per week did not enhance outcomes across any domain, and small differences favoring CON over 3INT were observed in muscular fitness, indicating that a higher nominal

dose did not translate into greater benefits under real-world school conditions. These findings suggest that the maximum feasible dose of FF10 is not necessarily the optimal dose, as higher intervention frequency may compromise implementation quality. The achieved intervention period was shorter than intended, which should be considered when interpreting

the observed effects. No between-group differences were observed for cardiorespiratory fitness, blood pressure, or psychosocial measures.

4.1 | Cardiorespiratory Fitness

Contrary to our hypothesis, FF10 did not improve YYIR1C performance beyond usual PE, as all groups showed similar improvements over time. This finding aligns with previous school-based FIT FIRST trials reporting null effects of three weekly sessions in children and adolescents [16, 18], but contrasts with the Faroe Islands trial, where improvements were observed when three 40-min sessions were added on top of 60–120 min of compulsory PE and delivered exclusively by PE teachers [30]. Evidence from other PE-based interventions is also mixed: one Faroese 11-week school-based “11 for Health” trial with twice-weekly 45-min sessions for 10–12-year-old pupils reported no effects [31], whereas a Chinese school-based “11 for Health” trial found significant gains in cardiorespiratory fitness [19]. Differences in achieved implementation fidelity likely explain this heterogeneity across studies. Researcher-led protocols show that substantial YYIR1C improvements occur when a large proportion of session time is spent at high intensity [4], whereas sustaining such intensity in routine school PE without systematic monitoring is challenging. Evidence from broader HIIT and school-based PA research suggests that achieved intensity, rather than nominal session volume, is the primary driver of fitness adaptations [32]. In the present study, session intensity was not objectively assessed, as the focus was on weekly session frequency under real-world school conditions. Strategies such as intensity monitoring or researcher-led supervision were intentionally not implemented, as the aim was to evaluate dose–response effects within routine PE practice. Although such strategies may have increased achieved intensity, they would likely have reduced ecological validity and relevance for large-scale implementation.

Teacher unfamiliarity with the programme, organizational demands, and competing curricular priorities—potentially reflected in the low teacher motivation scores—may have limited implementation fidelity and opportunities for sustained high-intensity activity [10, 20]. This is further supported by the greater substitution of regular PE lessons with FF10 in the 3INT group. Even among PE-trained teachers, such constraints may reduce adherence to the intended session structure and intensity, thereby attenuating intervention effects on cardiorespiratory fitness. These findings suggest that future refinements may benefit from a stronger emphasis on pedagogical approaches during teacher training, rather than on device-based monitoring. Equipping teachers with flexible adaptation strategies—such as modifying rules, group sizes, or equipment, and using verbal encouragement to sustain movement—may support higher activity levels while preserving the play-based and inclusive nature of school PE. In addition, regular lesson observations and ongoing teacher support (e.g., online guidance and practical tips) may further enhance implementation fidelity.

4.2 | Cardiometabolic Health

The 1.5INT arm showed small but more favorable changes in body composition than CON, with smaller gains in body fat

and BMI. Even small reductions in adiposity during childhood are clinically relevant given their links to later cardiometabolic risk [5, 33]. These findings contrast with much of the school-based PA literature, where BMI and FMI often remain unchanged. The absence of similar effects in 3INT may reflect implementation rather than nominal dose: more 1.5INT classes delivered FF10 in addition to PE, whereas most 3INT classes integrated FF10 within existing PE, likely compressing overall weekly exposure or intensity [20]. Previous FIT FIRST trials have reported mixed body-composition effects: Danish studies reported null findings at 10 weeks and 10 months [17, 18], whereas the Faroe Islands study reported favorable changes in body fat percentage [30]. Single-sport “11 for Health” programmes have more consistently improved adiposity in Danish and Faroese children [31, 34]. Feasible, timetable-friendly doses appear critical; systematic monitoring of intensity and session content may help to better understand and optimize potential effects.

No between-group effects were observed for blood pressure. A 10-month FIT FIRST programme reduced diastolic blood pressure [16], whereas shorter trials show mixed or null effects [18, 30]. “11 for Health” has lowered blood pressure in some settings [19, 31], possibly due to its integrated health-education content, which may influence behaviors beyond sessions. In the present study, the absence of effects highlights the difficulty of shifting blood pressure in generally healthy, normotensive children and may suggest that longer, more targeted, or multi-component interventions are required, particularly given that the intervention was not delivered for the full planned 20-week period.

The small within-group reduction in RHR in 3INT, without significant between-group differences, aligns with other FIT FIRST studies in primary-school samples [16, 19, 30, 31], whereas changes in RHR have been observed in older cohorts [18].

4.3 | Muscular Fitness

SLJ improved across all groups, with larger gains in CON than in the intervention arms, indicating no added effect of FF10 beyond usual PE. Possible explanations include limited task specificity (aerobic, game-based activity rather than jump-focused high-velocity loading) and the coordination demands of the paused SLJ protocol, which may mask power gains. A previous 10-month small-sided ball-game trial in a similar age group reported SLJ improvements [17], suggesting that longer exposure and more targeted progression may be needed. Null or selective effects in other FIT FIRST and “11 for Health” studies similarly may point to specificity and progression as key determinants of jump performance [18, 30, 35].

AAT performance improved over time in all groups, with no between-group differences observed. In contrast, a Faroese FIT FIRST trial reported improvements in agility performance following an intervention delivered as three weekly sessions in addition to regular PE and led exclusively by PE-trained teachers, reflecting a higher weekly dose than in the present study [30]. This difference in intervention dose may partly

explain the discrepant findings. Additional explanations include differences in session frequency and agility-specific content between studies, as well as potential differences in familiarization effects, given that AAT performance relies heavily on coordination and rapid change-of-direction ability. In the present FF10 intervention, agility-specific adaptations may have been diluted by the multisport format, in which many activities involve ball handling and place greater demands on coordination and technical skills than on pure speed. Furthermore, although teachers were encouraged to sample all 10 sports, session content and repetition were not systematically monitored, which may have limited stimulus specificity and subsequent agility adaptations.

Postural balance improved more in CON than in both FF10 arms. “11 for Health” and a 10-month FF10 trial have reported positive balance effects using more targeted balance tasks or different outcome measures (e.g., falls per minute) [17, 19, 31]. Our findings may support the view that balance improvements may depend on targeted content rather than general exposure to diverse activities.

Handgrip strength increased in all groups, with greater gains in 1.5INT than in CON and 3INT, suggesting that FF10’s ball-game format may contribute to upper-body strength within regular lessons. A plausible mechanism is the repeated loading of the hand–forearm complex through catching, throwing, and ball control. The smaller gain in 3INT again emphasizes that more sessions do not automatically translate into a stronger stimulus, suggesting that a higher nominal dose may exceed the optimal dose when implementation quality cannot be maintained.

Absolute and relative muscle mass increased across all groups, with no between-group effects. In this age range, gains in lean mass largely reflect growth and maturation rather than training-induced hypertrophy. Accordingly, the FF10 stimulus may not have been sufficient to elicit additional lean mass accrual beyond normal developmental changes.

4.4 | Psychosocial Well-Being

From a theoretical perspective, psychosocial benefits of school-based PA depend not only on exposure to activity, but also on need-supportive delivery that fosters choice, perceived competence, and relatedness [36]. While FF10 incorporates inclusive, team-based activities, its structured and teacher-led design requires adherence to prespecified activities outlined in the manuals to ensure high-intensity participation. This necessary standardization may limit opportunities for child autonomy, potentially constraining effects on HRQoL and physical self-concept. Although such psychosocial dimensions may be less sensitive to change within a structured, fitness-oriented school intervention, they remain important for evaluating broader programme impact and understanding the conditions under which psychosocial benefits may emerge.

Consistent with this interpretation, we observed within-group improvements in selected KS-27 domains but no between-group differences. A recent 10-week FF10 study in the Faroe Islands reported improvements in Physical Well-being, particularly among

younger pupils, but similarly mixed effects across other HRQoL domains [37]. “11 for Health” has shown benefits in Physical Well-being and Social Support in some cohorts [38], highlighting that programme structure and context (single-sport vs. multisport, health education content, explicit social support, and peer interactions) may play an important role in shaping psychosocial outcomes.

Although FF10’s multisport format provides variety and may support competence and relatedness through simplified rules, achievable tasks, and small-team activities, its breadth-oriented and time-limited delivery may prioritize physical exposure over sustained psychological engagement. As a result, limited opportunities for reflection, choice, and repeated mastery within each activity may reduce the likelihood of detecting measurable changes in HRQoL and physical self-concept compared with usual PE lessons.

For the physical self-concept, no between-group effects across domains were observed, except for a significant Time × Group interaction in the perceived flexibility domain, with 3INT declining relative to CON, which improved from baseline to follow-up. These differences in perceived flexibility between CON and 3INT may reflect increased exposure to unfamiliar, high-intensity activities within a limited time frame. FF10 emphasizes vigorous, strength- and game-based activities delivered through small-sided formats and was not designed to target flexibility or recovery-focused elements. Consequently, higher training frequency may have increased transient muscle stiffness or soreness, which could negatively influence children’s subjective perceptions of flexibility.

Several factors may explain the overall null effects on psychosocial outcomes. Similar patterns have been observed in a 10-week FF10 study from the Faroe Islands, where self-perception outcomes assessed using the KIDSCREEN-52 favored the control group [37], suggesting that increased programme exposure does not necessarily translate into short-term psychosocial gains. First, early exposure to unfamiliar activities and self-report questionnaires may temporarily suppress perceived competence. Second, children in this sample had relatively high baseline self-perceptions, and larger changes are typically seen in those with lower starting levels [39]. Third, teacher motivation and the implementation climate were modest in the intervention arms, which can reduce pupil engagement and motivation [20, 40]. In addition, child-reported psychosocial questionnaires may be relatively insensitive to short-term change in younger age groups. Research indicates that children aged 7–11 years are still developing cognitive, linguistic, and metacognitive skills, which can limit their ability to detect and consistently report subtle changes in abstract constructs such as well-being or self-concept over short intervention periods [28]. Consequently, null findings on psychosocial outcomes in school-based PA trials may partly reflect measurement limitations rather than the absence of meaningful effects.

4.5 | Strengths and Limitations of the Study

This study provides the first evaluation of the multisport FF10 programme in 7–11-year-olds across fitness, health, and

well-being. Key strengths include the large sample size, the cluster-randomized design, and delivery by both PE-trained and non-PE teachers within routine school settings using standardized training, manuals, and equipment, supporting reasonable generalisability to Danish primary schools.

Several limitations should be acknowledged. Implementation fidelity varied between intervention arms, with poorer adherence and shorter delivery periods than planned, which likely attenuated expected intervention effects across outcomes. Time and facility constraints increased organizational demands at higher session frequencies, and modest teacher motivation scores may have compromised delivery quality, including among PE-trained teachers [20]. We lacked device-based monitoring of PA and session intensity, did not control for diet, and could not isolate specific mechanisms within this multisport programme. The use of an active control condition, seasonal timing (winter baseline and summer follow-up), and maturational factors in this age group likely attenuated between-group contrasts, as the control group continued usual PE that may have provided meaningful PA. Ceiling effects may also have limited observable intervention effects, as FF10 was delivered as a universal school-based programme, and some pupils may have had high baseline levels of fitness or psychosocial well-being, particularly for outcomes with restricted variability in generally healthy child populations.

Finally, school-level or area-level socioeconomic status indicators were not included in the study, limiting the assessment of differential effects across socioeconomic contexts. In addition, analyses of secondary outcomes were exploratory and conducted without adjustment for multiple comparisons; these findings should therefore be interpreted with caution.

5 | Conclusion

In this 4-month cluster-randomized controlled trial involving schoolchildren aged 7–11 years, a moderate multisport FF10 dose (1.5 sessions per week) produced small improvements in body composition and handgrip strength under real-world school conditions. No between-group effects were observed for cardiorespiratory fitness (the primary outcome) or for psychosocial, cardiovascular, or other muscular fitness measures. Increasing the intervention frequency to three sessions per week did not enhance outcomes. Overall, these findings indicate that moderate, feasible doses may outperform higher-frequency implementations when delivered under real-world constraints.

6 | Perspectives

The present study shows that integrating about 1.5 multisport FF10 sessions per week is feasible within Danish school timetables and can yield selective fitness and health benefits. The intervention groups delivered the programme for 3–4 months and not the full 20-week period, highlighting implementation challenges typical of real-world school-based PA interventions. Although FF10 is supported by accessible manuals,

ready-made lesson plans, and brief teacher training, maintaining implementation quality is more challenging as session frequency increases. Future research would benefit from qualitative and mixed-method approaches to better understand implementation processes in school settings. Interviews or focus groups with teachers and pupils could provide insights into barriers, facilitators, and context-specific adaptations. The absence of positive psychosocial outcomes suggests that FF10, irrespective of session frequency, as implemented, was insufficient to influence these domains, and a further development of the concept to empower motivational climate and promote basic psychological needs satisfaction. Taken together with evidence from previous FIT FIRST and “11 for Health” trials, FF10 delivered 1.5 times per week may represent a scalable and time-friendly supplement to, or partial replacement for, usual PE. Whether this delivery model supports sustained long-term health gains in primary school children remains to be established longitudinally.

Author Contributions

C.E. led school recruitment, testing, and school coordination, delivered teacher training, analyzed the data, drafted the manuscript, revised it, and approved the final version. M.N.L. contributed to study design, teacher training, and data collection, contributed to the original draft, revised the manuscript, and approved the final version. S.K., C.B.M., and C.C. conducted testing, revised the manuscript, and approved the final version. G.T. conducted testing, analyzed the data, contributed to the original draft, revised the manuscript, and approved the final version. L.B.C., C.T.N., and N.N. contributed to the design and funding of the study, revised the manuscript, and approved the final version. P.K. designed the study, applied for funding, took part in school recruitment, contributed to the original draft, revised the manuscript, approved the final version, and serves as guarantor.

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Disclosure

Protocol and Statistical Analysis Plan: The trial was registered at [ClinicalTrials.gov](https://clinicaltrials.gov) under identifier NCT06180772 on 12 December 2022. The full protocol is not publicly posted; the registry record provides key methodological details. The prespecified Statistical Analysis Plan is held by the authors and is available from the corresponding author on reasonable request.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Appendix S1:** sms70311-sup-0001-AppendixS1.docx. CONSORT checklist. Completed CONSORT 2025 checklist for cluster RCTs. **Appendix S2:** sms70311-sup-0002-AppendixS2.docx. Warm-up protocol. Full procedures for the standardized warm-up,

performed prior to the physical tests. **Appendix S3:** sms70311-sup-0003-AppendixS3.docx. Outlier rules. Outlier handling across outcomes. **Appendix S4:** sms70311-sup-0004-AppendixS4.docx. Model outputs & ICCs. Full model outputs and per-outcome class-level ICCs for each outcome variable. **Appendix S5:** sms70311-sup-0005-AppendixS5.docx. Within-group changes. Adjusted follow-up—baseline differences for each outcome variable by group. **Appendix S6:** sms70311-sup-0006-AppendixS6.docx. Consent form. Parental consent form (English and Danish).