Study Protocol and Statistical Analysis Plan

Official Title: Effectiveness of an Adapted Basketball Program With and Without Video Support in Adolescents With Obesity: A Randomized Controlled Trial

Brief Title: Effectiveness of Adapted Basketball Programs in Adolescents With Obesity (ABBA)

Overall Status: Completed
Study Start: June 1, 2024
Primary Completion: January 1, 2025
Study Completion: February 1, 2025
Record Verification: June 2025

Principal Investigator: Antonella Muscella
University of Sfax
University of Salento

Study Description

This randomized controlled trial (RCT) includes three parallel intervention arms designed to evaluate the effects of different basketball teaching programs on adolescents with obesity. The intervention spans seven consecutive weeks and consists of one structured basketball session per week, each lasting 60 minutes and delivered during regular physical education (PE) classes. A total of 55 adolescents (33 females and 22 males), aged 15 to 17 years and classified as having moderate obesity (BMI: 30–34.9 kg/m²), were recruited from a secondary school in the Sidi Bouzid region of Tunisia. Participants were randomly assigned using a computer-generated sequence to one of the following groups:

• ADAPT+VID Group (n = 19): An adapted basketball program enriched with pre-session instructional video summaries.

• ADAPT Group (n = 18): The same adapted basketball program without video supplementation.

• CONT Group (n = 18): A traditional basketball program without pedagogical modifications.

Pre- (T0) and post-intervention (T1) assessments included: (i) anthropometric measurements (BMI), (ii) physical fitness tests, (iii) evaluations of technical basketball performance (passing, dribbling, shooting), and (iv) assessments of motivation. Motivation was assessed following the first and final sessions. Each session was structured into three phases: a standardized warm-up (15 minutes), a main instructional phase (40 minutes), and a cool-down period (5 minutes). The adapted program was tailored to the specific needs of adolescents with obesity by modifying drills, reducing competitiveness, and incorporating extended recovery and instructional periods. Pre-session videos in the ADAPT+VID group were uploaded to a private Facebook group 48 hours prior to each session and engagement was monitored. The study received approval from the appropriate institutional ethics committee and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants and their legal guardians prior to enrollment.

Approved Approval Number: 048/2022 by Ethics Committee of the Faculty of Medicine of Sfax Faculty of Medicine of Sfax Phone: 74 241 888

1. **Study Design** –

Study Type: Randomized Controlled Trial (RCT) –

Number of Arms: Three –

- Allocation: Randomized –

Duration: 12-week intervention with 1-month follow-up

2. **Study Population**

Inclusion Criteria

Adolescents aged 15 to 17 years - BMI between 30-34.9 kg/m² (moderate obesity) - No musculoskeletal, neurological, or orthopedic conditions affecting physical performance in the last 6 months - Normal or corrected-to-normal vision - Regular attendance in PE classes - Provided informed consent from legal guardians

Exclusion Criteria:

Musculoskeletal, neurological, or orthopedic disorders impairing physical performance - Visual impairments not corrected to normal vision - Irregular PE attendance - Participation in other structured physical activity programs

3. **Interventions**

Parallel Assignment Three-arm parallel-group randomized controlled trial. Participants were randomly assigned to one of three intervention arms: (i) an adapted basketball program with pre-session video summaries (ADAPT+VID), (ii) an adapted basketball program without video supplementation (ADAPT), or (iii) a traditional basketball program without specific pedagogical modifications (CONT).

4. **Outcome Measures**

a) Change in Physical Fitness (Spartacus Test), Week 0 to 13 2.
b) Change in Technical Skills (passing, shooting, dribbling), Week 0 to 13 3.
c) Change in Motivation (SIMS), Session 1 and 7
d) BMI and Body Composition, Week 0 to 13

Primary Outcome Measure: 1. Change in Body Mass Index (BMI) in kg/m² Body Mass Index (BMI) will be calculated using the formula: weight (kg) / height (m²). Weight will be measured using a calibrated digital scale and height using a wall-mounted stadiometer. BMI will be assessed at baseline and after 7 weeks to evaluate the effects of the basketball training intervention on body composition in adolescents with moderate obesity

Secondary Outcome Measure: 2. Change in Cardiorespiratory Fitness Assessed by Intermittent Fitness Test 15-15. -Unit of Measure: Meters (total distance covered) (Spartacus Test). -Unit of Measure: Meters (total distance covered) Cardiorespiratory fitness will be assessed using the 15-15 intermittent fitness test (Spartacus Test), a shuttle run test designed for overweight and obese

adolescents. The test involves 15-second running intervals alternated with 15- second passive recovery over a 40-meter distance, with progressive speed increases starting at 5 km/h and increasing by 0.5 km/h per stage. The test concludes when the participant fails to maintain pace for two consecutive intervals or stops due to fatigue. The total distance covered will be used to estimate cardiorespiratory fitness (VO2peak). The Spartacus test is validated for this population and demonstrates high test-retest reliability
(ICC > 0.90).

Change in Situational Motivation (SIMS) Scores. -

Motivation was assessed using the Situational Motivation Scale (SIMS), a validated 16-item questionnaire evaluating four subdimensions: intrinsic motivation, identified regulation, external regulation, and amotivation. Each item is rated on a 7-point Likert scale (1 = "does not correspond at all" to 7 = "corresponds exactly"). The average score for each subscale was calculated by averaging the corresponding four items (e.g., intrinsic motivation: items 1, 5, 9, 13). Higher scores indicate greater intensity of the respective motivation type. Units on the Situational Motivation Scale (SIMS), a 7-point Likert scale with minimum score 1 and maximum score 7.

Change in Passing Accuracy in Basketball. –

Passing accuracy was evaluated using the AAHPERD Passing Test, which requires participants to perform chest passes at six wall targets within 30 seconds. Points are awarded based on precision and rule compliance. The total score is the sum of two scored trials, after one practice attempt. This test has demonstrated strong reliability (r = 0.84– 0.97).

Change in Shooting Accuracy in Basketball –

Shooting accuracy was assessed using a standardized 10-shot free-throw test from the 4.57-meter line, using FIBAapproved size 6 basketballs. Each shot was scored using a 6-level scale (0–5 points), considering precision and shot quality. Total score was calculated by summing the scores of the 10 attempts

Change in Dribbling Performance in Basketball. –

Dribbling proficiency was evaluated using a timed zigzag cone course (5 cones, 2 meters apart). Participants completed a round-trip dribbling trial; the best of two attempts was retained. Performance was measured in seconds using a stopwatch accurate to 0.01 seconds.

5. Study Schedule

- Week 0: Baseline
- Weeks 1-12: Intervention

- Week 13: Post-intervention
- Week 16: Follow-up

6. Data Collection and Management

Standardized tools will be used. Data anonymized and stored on a secure server. Only authorized researchers will have access.

7. Statistical analyses

Statistical analyses were performed using Statistica 10 software (StatSoft, Krakow, Poland). The Shapiro-Wilk test confirmed that all variables satisfied the normality assumption and the Levene test confirmed the homogeneity of the data and therefore the suitability of the ANOVA model for intergroup comparisons. To analyze the changes in the parameters under examination, a repeated measures ANOVA was conducted involving three groups (ADAPT+VID, ADAPT, and CONT) and two measurement periods (before [T0] and after intervention [T1]). Effect sizes were calculated using partial eta squared (η^2) and interpreted as small (0.01), medium (0.06), or large (0.14). Post-hoc comparisons were performed applying the Bonferroni correction to identify significant mean differences between groups.

Additionally, effect sizes were calculated using Cohen's d method, with interpretation according to Cohen's classification: values of $d \geq 0.2$ indicating a small effect, $d \geq 0.5$ a moderate effect, and $d \geq 0.8$ a large effect. Statistical significance was set at $p < 0.05$.

MODELE DE CONSENTEMENT ECLAIRE
DESTINE AU TUTEUR LEGAL DU PARTICIPANT MINEUR
A UN PROJET DE RECHERCHE

Titre du projet de recherche : Impact des différentes méthodes d'utilisation des outils technologiques éducatifs sur l'apprentissage des mouvements sportifs complexes pendant les cours d'éducation physique chez des élèves
Investigateur Principal : Mohamed Abdelkader Souissi

J'ai pris connaissance de la lettre d'information. Je déclare avoir obtenu des explications sur le projet et avoir reçu des réponses à mes questions. J'ai eu le temps nécessaire pour prendre une décision.

J'ai été informé (e), oralement et par écrit, des objectifs du projet, de ses méthodes de recueil des données et de leur utilisation ainsi que des modalités de la participation de mon fils au projet.
J'ai également été informé(e) :

1- de la façon dont les chercheurs assureront la confidentialité des données concernant mon fils **ainsi que des noms des personnes qui en sont responsables.**
2- Du droit de mon fils, de s'en retirer à tout moment si je le juge nécessaire sans que cela ne lui occasionne un quelconque préjudice.
3- de mon droit de contacter, si j'ai des questions sur le projet, l'Investigateur Principal du projet **Mohamed Abdelkader Souissi** et numéro de téléphone **96366344**.

J'ai l'assurance que les propos recueillis au cours de cet entretien seront traités de façon confidentielle et anonyme.

Je soussigné :
Nom:……**Prénom :** …….
Tuteur du participant :
Nom :…… **Prénom :** ……...
En ma qualité de :…… …….....
Je consens à la participation de mon fils à ce projet de recherche aux conditions qui y sont énoncées.
Je peux retirer mon fils de ce projet à n'importe quel moment, sans en donner les raisons, en faisant connaître ma décision à l'Investigateur Principal ou à son mandataire désigné. J'ai aussi été informé(e) que la participation de mon fils à ce projet pourra être interrompue sans mon accord préalable, et ce dans certains cas tels que définis dans la lettre d'information.
Je conserverai un exemplaire de la lettre d'information et du formulaire de consentement dûment rempli et signé par moi-même et l'Investigateur Principal.
Pour les échantillons/ données collectés :

- j'autorise leur transfert dans le cadre du présent projet vers une autre structure/un autre laboratoire :
  * En Tunisie : ☐ Oui ☐ Non
  * A l'étranger : ☐ Oui ☐ Non
- j'autorise leur publication de façon anonyme dans les revues scientifiques : ☐ Oui ☐ Non
- je demande leur destruction à la clôture du présent projet : Oui ☐ Non ☐
- j'autorise leur conservation après la clôture du projet en vue de leur réutilisation :
  * pour des projets portant uniquement sur le même thème (les indiquer) : Oui ☐ Non ☐

……
  * ou pour d'autres projets de recherche : Oui ☐ Non ☐

J'ai compris que toute réutilisation ou transfert des échantillons / données de mon fils ne se fera qu'après l'avis favorable d'un Comité d'Éthique.

Signature : ……**Date :** ……

:.....

<u>A compléter par le participant mineur assenti</u>:

Je soussigné :

Nom : ……**Prénom :** ……

Je consens à participer à ce projet de recherche aux conditions qui y sont énoncées.
Je peux me retirer de ce projet à n'importe quel moment, sans en donner les raisons, en faisant connaître ma décision à l'Investigateur Principal ou à son mandataire désigné.
J'ai aussi été informé(e) que ma participation à ce projet pourra être interrompue sans mon accord préalable, et ce dans certains cas tels que définis dans la lettre d'information.
Je conserverai un exemplaire de la lettre d'information et du formulaire de consentement dûment rempli et signé par moi-même et par l'Investigateur Principal.
Pour mes données / échantillons collectés :

- j'autorise leur transfert dans le cadre du présent projet vers une autre structure/un autre laboratoire :
  * En Tunisie ☐ Oui ☐ Non
  * A l'étranger : ☐ Oui ☐ Non
- j'autorise leur publication de façon anonyme dans les revues scientifiques : ☐ Oui ☐ Non
- je demande leur destruction à la clôture du présent projet : Oui ☐ Non ☐
- j'autorise leur conservation après la clôture du projet en vue de leur réutilisation :
  * pour des projets portant uniquement sur le même thème (les indiquer): Oui ☐ Non ☐

……
  * ou pour d'autres projets de recherche : Oui ☐ Non ☐

J'ai compris que toute réutilisation ou transfert de mes échantillons / données ne se fera qu'après l'avis favorable d'un Comité d'Éthique.

Signature :……**Date :**……

<u>A compléter par le témoin*</u> : non obligatoire

Je soussigné(e) :

Nom :……**Prénom :** ……

Témoin de l'entretien du tuteur du participant…….... **avec l'investigateur Principal ou à son mandataire désigné.**

Je certifie que le tuteur du participant mineur à la recherche a reçu les explications relatives aux éléments contenus dans la lettre d'information et dans le formulaire de consentement, qu'il a obtenu des réponses aux questions qu'il a posées et qu'il demeure libre de mettre un terme à sa participation, et ce, sans préjudice.

Témoin en sa qualité de :

- Parent (e) du participant : Oui ☐ Non ☐
  Si oui, préciser le lien de parenté :…….
- Autres : ☐ Préciser la qualité :…… …….

Signature : ……..... **Date :** ……

N.B : Le témoin ne doit pas faire partie de l'équipe de recherche ou du corps médical et paramédical engagée dans le projet de recherche.

:……..

INFORMED CONSENT FORM
FOR THE LEGAL GUARDIAN OF A MINOR PARTICIPANT
IN A RESEARCH PROJECT

Research Project Title: Impact of Different Methods of Using Educational Technology Tools on the Learning of Complex Sports Movements in Physical Education Classes Among Students
Principal Investigator: : Mohamed Abdelkader Souissi

I have read the information letter. I declare that I have received explanations about the project and answers to my questions. I have had sufficient time to make my decision.

I have been informed, both orally and in writing, about the objectives of the project, its data collection methods and usage, as well as the conditions of my child's participation in the project.

1. How the researchers will ensure the confidentiality of my child's data, as well as the names of the individuals responsible for it.
2. My child's right to withdraw from the project at any time if I deem it necessary, without any consequences or disadvantages.
3. My right to contact the Principal Investigator of the project, Mohamed Abdelkader Souissi, at the phone number 0021696366344 if I have any questions about the project.

I am assured that all information collected during this interview will be treated confidentially and anonymously.

I, the undersigned:
Name: …… First name: ……
Legal guardian of the participant:
Name: …… First name: ……
In my capacity as: ………….....
I consent to my child's participation in this research project under the stated conditions.
I understand that I may withdraw my child from this project at any time, without providing a reason, by informing the Principal Investigator or their designated representative of my decision. I have also been informed that my child's participation in this project may be discontinued without my prior consent in certain cases, as defined in the information letter.
I will keep a copy of the information letter and the consent form, duly completed and signed by both myself and the Principal Investigator.
For the collected samples/data:

- I authorize their transfer, within the framework of this project, to another institution/laboratory:
  * In Tunisia:: ☐ Yes ☐ No
  * Abroad: ☐ Yes ☐ No

• I authorize their anonymous publication in scientific journals: ☐ Yes ☐ No
• I request their destruction at the conclusion of this project: ☐ Yes ☐ No
• I authorize their retention after the conclusion of the project for potential reuse:

- For projects related exclusively to the same theme (please specify): ☐ Yes ☐ No
  ……
  ……

:.....

- Or for other research projects: ☐ Yes ☐ No

I understand that any reuse or transfer of my child's samples/data will only occur after receiving approval from an Ethics Committee.

Signature : ……**Date :** ……

To be completed by the minor participant

I, the undersigned:
Name: ……
First Name: ……

I consent to participate in this research project under the conditions outlined.
I understand that I may withdraw from this project at any time, without providing a reason, by informing the Principal Investigator or their designated representative.
I have also been informed that my participation in this project may be interrupted without my prior consent, in certain cases as defined in the information letter.
I will keep a copy of the information letter and the consent form, duly completed and signed by myself and the Principal Investigator.

For my data/samples collected:
• I authorize their transfer, within the framework of this project, to another institution/laboratory:

- In Tunisia: ☐ Yes ☐ No
- Abroad: ☐ Yes ☐ No
  • I authorize their anonymous publication in scientific journals: ☐ Yes ☐ No
  • I request their destruction at the conclusion of this project: ☐ Yes ☐ No
  • I authorize their retention after the conclusion of the project for potential reuse:
- For projects related exclusively to the same theme (please specify): ☐ Yes ☐ No
  ……
- Or for other research projects: ☐ Yes ☐ No

I understand that any reuse or transfer of my samples/data will only occur after receiving approval from

:.....

an Ethics Committee.

Signature: ……
Date: ……

To be completed by the witness* (optional):

I, the undersigned:
Name: ……
First Name: ……

Witness to the meeting between the legal guardian of the participant …… and the Principal Investigator or their designated representative.

I certify that the legal guardian of the minor participant in the research has received explanations about the elements contained in the information letter and the consent form, that they have obtained answers to the questions they asked, and that they remain free to terminate their participation, without any prejudice.

Witness in their capacity as:
• Parent of the participant: ☐ Yes ☐ No
If yes, specify the relationship: …….
• Other: Specify the role: …….

Signature: …….....
Date: ……

Note: The witness must not be part of the research team or the medical and paramedical staff involved in the research project.

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