



Rationale and design of a pilot randomized controlled trial to increase moderate-to-vigorous physical activity in preadolescent Latina girls and their mothers

Elva M. Arredondo^{a,*}, Jennifer Schneider^b, Marisa Torres-Ruiz^c, Victoria Telles^c, Katie Thralls Butte^d, Michelle West^e, Miriam Maldonado^e, Kathleen Gallagher^f, Scott Roesch^a, Guadalupe X. Ayala^e, Tom Baranowski^g

^a Psychology Department, San Diego State University, USA

^b School of Public Health, San Diego State University Foundation, USA

^c Joint Doctoral Program (JDP) in Public Health at San Diego State University (SDSU), The University of California, San Diego, USA

^d Health and Human Performance, Seattle Pacific University, USA

^e School of Public Health, San Diego State University, USA

^f Baker Elementary School, USA

^g Pediatrics-Nutrition, Baylor College of Medicines, USA

ARTICLE INFO

Keywords:

Dyadic intervention
Hispanic/Latinos
Health promotion
Exercise
Health equity

ABSTRACT

Background: Hispanic/Latina girls have a low prevalence of moderate-intensity physical activity (PA) compared to their male counterparts and non-Hispanic White girls. Mothers influence their children's activity levels by creating and supporting PA opportunities, modeling PA, and reinforcing children's efforts to be physically active. The *Connigo* trial will evaluate a mother-daughter intervention to promote PA and examine potential mechanisms of change including mothers' PA, parenting regarding PA, and mother-daughter communication.

Method: This randomized controlled trial examines the feasibility, acceptability, and impact of a 12-week intervention promoting PA in preadolescent Latina girls in San Diego County, CA. Participants (n = 90 dyads) are randomized to the *Connigo* PA intervention or to a control group that receive an abbreviated version of the intervention. The intervention was informed by Social Cognitive Theory and Family Systems Theory and emphasize family-level factors to promote PA using an actor-partner model. Mothers and daughters attend weekly 90-min sessions in English or in Spanish via Zoom video conferencing, supported by facilitator follow-ups and WhatsApp supportive chat group for mothers. Objective (accelerometer) and self-report measures at baseline, 3 months, and 6 months capture the frequency and intensity of PA and correlates and predictors of PA. We also examine the impact of the intervention on the bidirectional influence of mother-daughter PA.

Implications: The findings from the *Connigo* trial will form the basis of a randomized controlled community trial and will move the field forward in identifying targets of change in preventing chronic disease risk in Hispanic/Latino communities.

1. Introduction

Insufficient physical activity (PA) is a key risk factor for cardiovascular disease, cancer, and mental health problems, and is one of the leading risk factors for death worldwide [1–4]. However, only a quarter of US adolescents meet current PA guidelines [5], with fewer girls (18%) meeting the guidelines than boys (35%) [6]. These trends continue into adulthood with a pronounced decline in girls' PA during adolescence [7,

8], due to the biological, mental, and social changes during puberty [9–11]. Intervening before puberty (typically between ages 8–11 years old) and targeting factors that influence PA in girls will help curb the steep drop off in PA during adolescence and shape girls' PA behaviors for adulthood [12,13]. Sociocultural factors, including immigrant experiences, family expectations, acculturation, dietary practices, and other environmental factors help to explain the low rates of PA among Latinas [14,15].

* Corresponding author.

E-mail address: earredon@sdsu.edu (E.M. Arredondo).

<https://doi.org/10.1016/j.conctc.2023.101137>

Received 26 October 2022; Received in revised form 8 April 2023; Accepted 11 April 2023

Available online 20 April 2023

2451-8654/© 2023 Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Mothers are instrumental in promoting healthy behaviors in their daughters [16]. Family Systems Theory (FST) proposes that positive parenting skills, including providing social support, practicing positive communication styles, and engaging in monitoring and limit setting facilitate health behavior change [17]. Mothers can create and support PA opportunities, reduce access to sedentary activities, model PA, and reinforce daughters to be physically active [18,19]. Growing evidence suggests that other family-level factors like parent-child communication positively predicts PA for girls [20]. Social Cognitive Theory (SCT) expands on FST in that it proposes that behavioral strategies, including goal setting, self-monitoring, and goal setting facilitate self-efficacy (self-confidence, competence) [21]. As such, SCT-informed interventions can be used to inform interventions that target individual health practices (e.g., monitoring one's physical activity) as well as family-level factors (e.g., setting goals to reinforce girls' PA, and communicate effectively between mothers and daughters) [22].

Parents are not parenting in isolation, but in response to children's traits and behaviors [23]. Children can play an important role in shaping PA parenting practices [24] and mothers' PA [24] through encouragement and support [25]. For example, children who request to go to the park for play may motivate mothers to be more active (e.g., walking to the park, playing in the park). Similarly, going on walks as a family or mother-daughter pair would provide opportunity to communicate, thereby strengthening the family bond. Understanding the bidirectional influence of daughters' and mothers' PA and other family factors will extend our understanding of the nature of parent-child relationships that may hinder or facilitate behavioral trajectories of PA [26,27].

Findings from systematic reviews show that mother-daughter interventions are promising in increasing daughters' PA, but that these studies had a high risk of bias due to methodological weaknesses (e.g., non-randomized studies, high attrition, and lack of device-based assessment, and many have not shown effects) [28]. Mother-daughter PA intervention studies that used rigorous study designs and assessments of PA (i.e. device-based assessments) did not report effects on preadolescents' PA [28]. Greater links between intervention approaches and FST constructs (e.g., parenting, family communication) may lead to bigger changes in the PA among family members [19,22,29–34]. These strategies may be particularly important for Latina girls and their mothers given cultural values like *familismo* (e.g., dedication, commitment, and loyalty to family) found in Latino families [35]. The current study *Connmigo* ('with me' in Spanish) addresses weaknesses of previous studies as it employs a randomized controlled design, uses device-based measures (e.g., accelerometers), targets key family level factors, and examines the bidirectional influence that mother-daughters have on each other's PA.

This manuscript describes the protocol of a pilot study designed to examine the feasibility and acceptability of the *Connmigo* intervention for promoting PA among Latina mothers and daughters [36]. In addition, we investigate the preliminary impact of the intervention of *Connmigo* on daughters' Moderate to Vigorous Physical Activity (MVPA). We also explore the influence of *Connmigo* on potential mechanisms of change such use of effective PA parenting practices and mother-daughter communication. *Connmigo* integrates FST and SCT by targeting parenting skills and practices in relation to PA, creating an environment supportive of PA, and modeling PA. We hypothesize that mothers in the intervention will report improved use of effective PA parenting strategies (reinforcement, nondirective support, etc.) and that mothers and daughters will report better mother-daughter communication compared to those in the waitlist control condition 3- and 6-months post-baseline. This manuscript will focus on the study design and protocols for recruitment, intervention delivery, data collection, and analyses.

2. Design and methods

2.1. Design

This 12-week pilot RCT tests the impact of a mother-daughter intervention to increase MVPA in preadolescent Latina girls and their mothers from San Diego, CA. Following baseline assessments, 90 dyads are randomized to a 12-week PA intervention (*Connmigo*) or waitlist control group. This study was approved by the Institutional Review Board of San Diego State University.

2.2. Setting & participants

To be eligible for the study, participants need to meet the following inclusion criteria: 1) a daughter between the ages of 8–11, 2) a daughter is not meeting CDC's 2018 PA guidelines (60-min MVPA/day) [37], 3) mother is the daughter's primary caregiver as defined by living with her 4 or more days out of the week, 4) mother and daughter both self-identify as Latina, 5) dyad can commit to attending program activities once weekly for 90 min over 12 weeks, 6) dyad plans to remain in the area for the study period, and 7) dyad has access to a laptop, mobile phone, or other devices that can connect to the internet. Potential participants are excluded based on the following criteria: 1) mother or daughter has a health condition precluding them from engaging in PA (assessed using the PA Readiness Questionnaire (PAR-Q+, and PAR-Q for Youth)) [38,39], 2) cognitive impairment preventing participation, or 3) inability to complete the informed consent in English or Spanish.

2.3. Procedures

2.3.1. Recruitment, screening, and enrollment

We partner with elementary schools and diverse community organizations throughout San Diego County, focusing on regions with a large Latino population. Organizations share our digital and paper flyers and help our group host virtual presentations with their members. Individuals who respond to recruitment invitations are directed to a Qualtrics XM webpage in English and Spanish with a video overview of the study, followed by a 9-question screener to determine preliminary eligibility (Fig. 1). Those who meet the eligibility criteria give their contact information and a research assistant follows up via phone to complete the PAR-Q+ [38]. Eligible individuals are enrolled in groups of 10–20 dyads, called waves, with a new wave starting every 2–4 months. At the start of a wave, all provided consent (mothers) and assent (daughters) and completed baseline assessment that included separate self-report surveys for mothers and daughters (described below) and accelerometer wear.

2.3.2. Randomization and enrollment

Following completion of the consent form and confirmation of accelerometer wear, participants are randomized to the two study arms (*Connmigo* intervention vs. waitlist control) by a random generator at a 1:1 ratio. Once randomized, participants are followed 3 and 6 months following baseline.

2.4. Intervention

2.4.1. Theoretical framework

The development of the *Connmigo* intervention was informed by Social Cognitive Theory (SCT) and Family Systems Theory (FST) [17,21]. SCT recognizes the reciprocal interaction that occurs between the individual (e.g., cognitions), environment (physical and social), and behavior (e.g., PA) (Fig. 2) FST posits that interactions between families and family contexts have a profound, bidirectional effect on their members' thoughts, feelings, and behaviors. The *Connmigo* intervention capitalizes on this bi-directionality and the unique bond that exists between Latina mothers and daughters and its potential to influence PA.

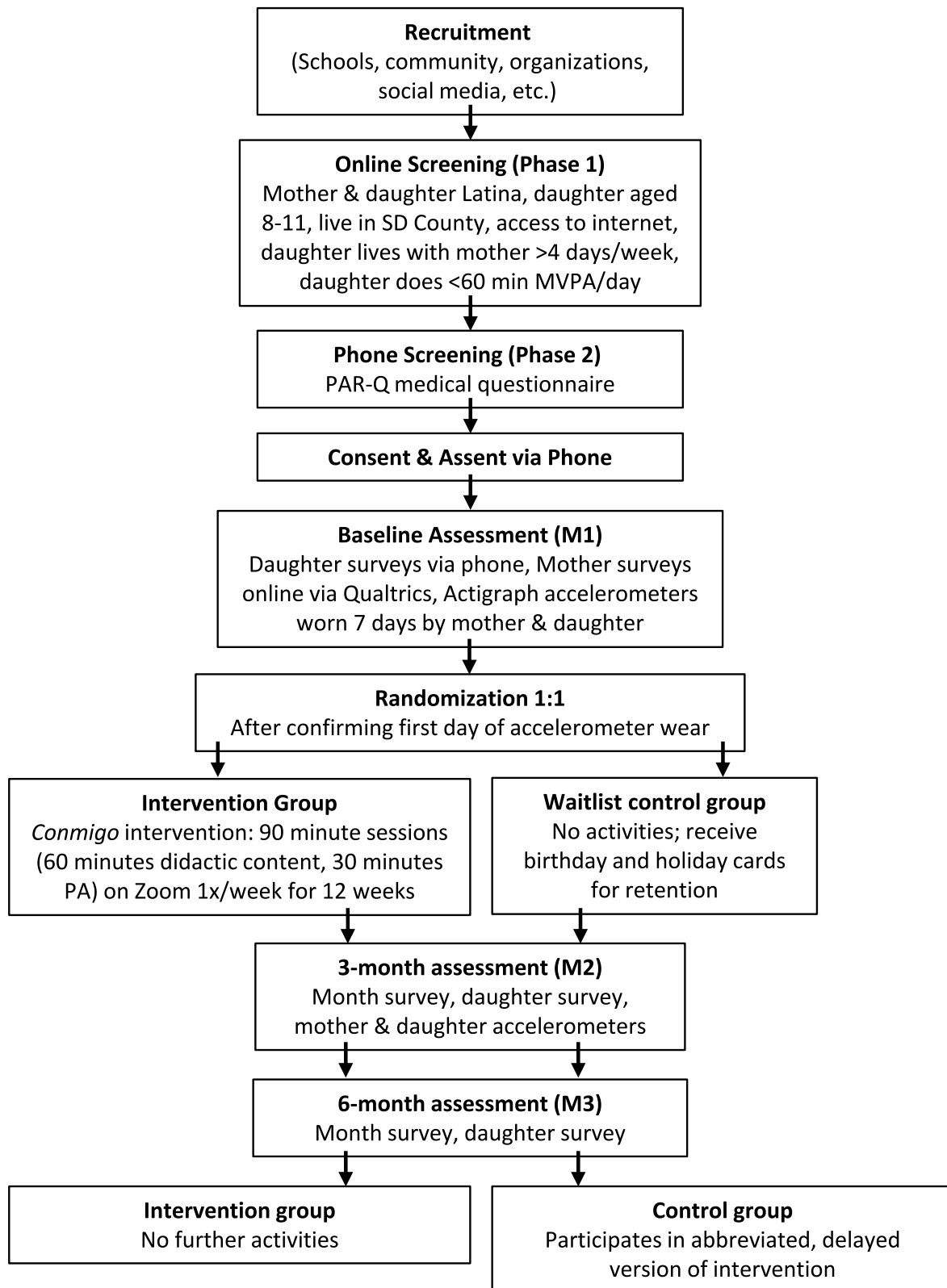


Fig. 1. Study design.

2.4.2. Intervention development

The intervention curriculum was adapted from a formative mother-daughter feasibility and acceptability study promoting PA in preadolescent Latinas [40]. We incorporated evidence based strategies targeting preadolescents [41–43] and results from focus groups with 10 Latina

mothers and their preadolescent daughters identifying key factors influencing young Latinas’ PA [40]. Further, Latino socio-cultural and environmental factors such as immigrant experiences, dietary practices, family expectations, parenting practices, barriers to PA, and communication practices informed the culturally-responsive curriculum content

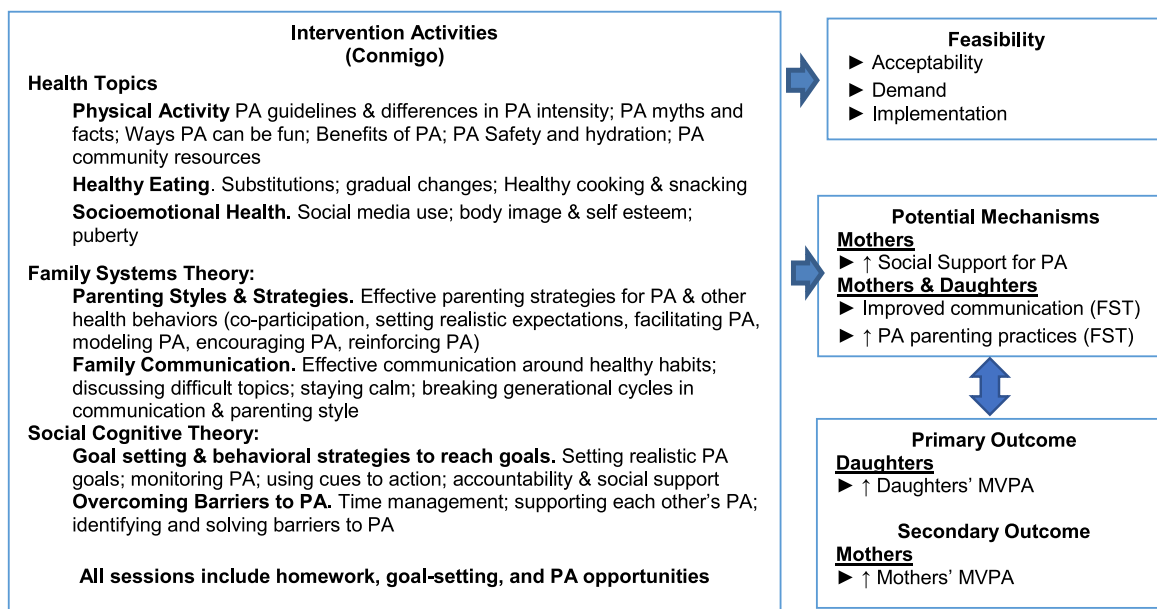


Fig. 2. Logic model.

of *Connigo*. *Connigo* incorporated strategies found to be successful in online PA programs such as monitoring, social support in group settings, PA homework, parental involvement, and incentives to encourage participation in PA outside of sessions [44,45]. Curriculum development was supported by an elementary education specialist who provided input to make activities age appropriate and engaging, as well as a Community Advisory Board with representatives including Latino parents and school administrators.

2.4.3. Intervention structure

The 12-week *Connigo* intervention consists of weekly 90-min sessions in English or Spanish via Zoom video conferencing; mothers and daughters participate together. The session structure was informed by our Community Advisory Board and Behavior Change Techniques Behavior Change Techniques [46]. Each session includes 30 min of PA guided by a trained PA specialist certified by the National Academy of Sports Medicine and 60 min of didactic content led by research staff on a variety of topics (Table 1). If participants miss a session, facilitators follow up via text with participants to schedule a one-on-one makeup session. When this is not possible to coordinate, the facilitator will send the weekly PowerPoint and notes for participants to review on their own. Participants are then reminded to attend the next session.

2.4.3.1. PA sessions. Each 30-min PA session consists of a warm-up (5-min), moderate-to-vigorous exercise (20-min), and a cool-down (5-min). They include a mixture of strength training and aerobic dance. The bilingual, bicultural PA specialist chooses music to appeal to young Latinas and incorporates culturally relevant rhythms and dance styles. Strength training exercises target different muscle groups (i.e. arms, legs, core) and use either body-weight or common household objects (e.g. towel, broom, belt, canned food) in place of formal exercise equipment. The PA specialist demonstrates exercises and modifications for each exercise to ensure appropriateness for the fitness level of the group. Participants are asked to keep their zoom cameras on so that the PA specialist can see participants and provide personalized feedback, motivation and encouragement to participants as they exercise.

2.4.3.2. Didactic content. Each didactic session consists of three main components: 1) weekly check ins, 2) culturally-responsive presentations reinforced by discussions and participatory activities, and 3) goal-setting and challenges (Table 1). Topics target SCT and FST

Table 1
Links between intervention strategies and theoretical domains.

Time	Intervention Component	Description	Theoretical Basis (Behavior Change Techniques)
30 min	Physical Activity	PA specialist role models & guides opportunities for dyads to engage in MVPA	SCT: Self-Efficacy for PA; Observational Learning(behavioral practice)
5–10 min	Weekly Check-ins	Dyads report weekly PA achievements; facilitators reinforce successes, provide encouragement, and help troubleshoot solutions to barriers to PA	SCT: Emotional Support, Reinforcement, Instrumental & Logistical support
40–50 min	Lesson Content	Content-based presentations, interactive discussions, and skill-building activities such as role-plays and planning behavior change	SCT: Self Efficacy, Social Support, Outcome Expectations FST: Communication, Parenting
5–10 min	Goal-setting	Guided SMART goal-setting activities and weekly challenges	SCT: Outcome Expectations, Self-Efficacy (problem solving, action planning)
Homework	Weekly PA challenges	Mother-daughter walks, creative PA opportunities, tracking PA	SCT: Outcome Expectations; Self-Efficacy, Social Support (practical/unspecified); Observational Learning/Role Modeling, Monitoring (feedback on behavior; social comparison)

constructs, and salient topics reported by our Community Advisory Board and participants during focus groups such as barriers to PA, nutrition, goal-setting, parenting practices, communication, and puberty (Table 2). Mothers and daughters participate together for the majority of sessions; for moms-only content (e.g. parenting), girls were dismissed early from the zoom meeting to go elsewhere in their homes.

Table 2
Intervention components and activities.

Week	Topic	Sub-Topics	Activities
1.	Physical Activity	<ul style="list-style-type: none"> Intro to program & justification PA benefits & guidelines PA safety & tips 	<ul style="list-style-type: none"> Icebreaker scavenger hunt True or False Jumping Jacks What's special about our relationship?
2.	Goal-setting	<ul style="list-style-type: none"> SMART goals Behavioral strategies to reach goals: monitoring, reminders, and social support Relapse 	<ul style="list-style-type: none"> Who sets goals? Guessing game SMART hand signals
3.	Parenting for PA	<ul style="list-style-type: none"> Kinds of PA Parenting strategies for PA: guided choice, reinforcement Parenting styles 	<ul style="list-style-type: none"> Would you Rather? Game Kinds of PA Race Planning & practicing applications Discussion
4.	Nutrition	<ul style="list-style-type: none"> Intro to Nutrition Substitutions Planning gradual changes 	<ul style="list-style-type: none"> What's in your kitchen? Game Let's make substitutions Activity Step-by-step Planning
5.	Social media	<ul style="list-style-type: none"> Screen Time Cyberbullying Comparison 	<ul style="list-style-type: none"> Discussion: how is being a teen different than 20 years ago?
6.	Overcoming barriers to PA	<ul style="list-style-type: none"> Barriers to PA Making time for PA PA with no equipment Making PA fun 	<ul style="list-style-type: none"> Discussion: what are your barriers? Videos: types of at-home PA Activity: household PA equipment
7.	Puberty	<ul style="list-style-type: none"> Puberty & PA Physical & emotional changes in adolescence Moms only: Parenting for puberty Mental Health 	<ul style="list-style-type: none"> How do you feel about it? Game Video: Am I normal? Discussion tips
8.	Mother-daughter communication	<ul style="list-style-type: none"> Non-verbal communication: tone of voice & body language Active listening 	<ul style="list-style-type: none"> Game: what is she feeling? Discussion & Role play
9.	Nutrition	<ul style="list-style-type: none"> Finding time to talk Hydration Sugar-sweetened drinks Parenting strategies for healthy eating: monitoring & limit setting 	<ul style="list-style-type: none"> Conversation tips Hydration game How much sugar? Demo Beverage substitutions
10.	Body image & self esteem	<ul style="list-style-type: none"> Body types & sizes Photoshop & body image Healthy friendship 	<ul style="list-style-type: none"> Dogs & healthy body types What I love about myself Game: Red light-green light friendship
11.	Mother-daughter communication; Parenting	<ul style="list-style-type: none"> Discussing difficult topics Mindful parenting 	<ul style="list-style-type: none"> What matters to you? Activity: how would you feel if ... Identifying triggers Role play
12.	Sustaining PA long-term	<ul style="list-style-type: none"> Setting long-term goals Plans for continued activity Resources for activity 	<ul style="list-style-type: none"> Review game & reflections Let's make a plan! Discussion: favorite ways to be active

At the start of the didactic session, facilitators checked in with participants about their weekly accomplishments, provide encouragement, reinforced successes, and facilitated troubleshooting of PA barriers. Check-ins provide accountability, social support, and the opportunity for participants to generate excitement for healthy behaviors by sharing their weekly accomplishments. The curriculum includes interactive games to engage girls and keep them moving and skill-building exercises to practice the weekly objective (e.g., planning food substitutions, SMART goal setting, role-playing parenting strategies). The sessions incorporate memes, short videos, comics, and movie clips to demonstrate concepts to engage participants. Culturally relevant examples are used throughout all materials (e.g., using traditional Latino foods in nutrition lessons, debunking common cultural myths).

At the end of each session, participants set SMART goals based on the topic of the week (e.g., I will offer my daughter PA choices twice this week); for homework, we assign two "PA challenges" of varying difficulty. Challenges require dyads to do PA between the sessions, and encourage *PA skill-building* (e.g., try a new sport, do a 30-min workout video, go for a mother-daughter walk), *building social support for PA* (e.g., invite a friend on a hike, do PA with the whole family), and *connecting with local resources* (e.g., visit a new park and play for an hour, visit your local rec center). Participants share photos of themselves completing the challenges and receive points each week for 1) completing challenges, 2) reaching goals, 3) attending sessions, and 4) any other PA they did together as a dyad. After week 6 and week 12, dyads receive prizes based on the number of points they accumulated, receiving bigger prizes (water bottle, tote bag, exercise towel) for more points.

2.4.4. Waitlist control condition

The control group participants received an asynchronous abbreviated version of the 12-week intervention group curriculum along with guided PA videos to access at their convenience following completion of the wave.

2.4.5. Technology: zoom and WhatsApp

All intervention sessions are delivered virtually with Zoom video conferencing. Participants could join via phone, computer, or tablet. Zoom allows participants to see the facilitators, the other participants, and the shared PowerPoint with program materials.

Participants (mothers) in the intervention condition join a WhatsApp groupchat. Facilitators use this to send weekly session reminders, allow participants to interact with one another, and share additional resources such as informational handouts with content relevant to the week's topic. Each week, participants share their goals in the group chat at the end of the session; during the week, they post photos of meeting their goals and accomplishing challenges.

2.5. Measures and materials

Participants complete a combination of device-based and self-report measures to capture the frequency and intensity of PA, as well as correlates and predictors of PA. Assessments are completed at baseline (M1), 3 months post baseline (M2, post-intervention), and 6 months post baseline (M3, sustainment). Participants are compensated at each measurement point; mothers received \$20 gift card and daughters chose between \$15 gift card or a prize valued at \$15.

2.5.1. Primary outcomes

Device-based measurement of girls' PA is the primary outcome for this study. Two triaxial Actigraph (GT3X+ & wGT3x-BT) devices were used to assess MVPA at baseline and 3 months post baseline. Devices are initialized in ActiLife Software (version 6.13.4) to collect raw acceleration at 30hz which is converted to 60-s epochs to use counts per minute (cpm) cut-points for data processing. After initialization, we mail the devices to mothers and daughters with written and video instructions to wear the device on their right hip, above the iliac crest with a fitted belt.

The device is to be worn during all waking hours; and removed in water (e.g., shower or pool) and when sleeping. Research staff calls participants to check in 2–3 days after the devices are mailed to clarify any questions. After 7 days of wear, the participants mail the device back or the research team schedule pick-ups at the participants' homes. Accelerometer wear is considered valid if worn for ≥3 days with ≥10hrs/day.

2.5.2. Self-report surveys

Mothers and daughters complete surveys at baseline, 3-, and 6-months post-baseline assessing several domains in the FST and SCT, primary and key secondary outcomes, socioemotional and demographic (Table 3). Mothers self-administer an electronic questionnaire. To ensure comprehension, daughters complete survey questionnaires over the phone with a trained research staff member who inputs the daughter's responses directly into Qualtrics XM webpage. Daughters are sent an electronic document with the questionnaire to follow along. All study questionnaires are created and distributed using Qualtrics XM.

2.5.3. Process evaluation and feasibility data

We collect data on acceptability, demand, and implementation based on metrics provided by Bowen and colleagues [36]. We will calculate recruitment rates (eligibility rates of those who expressed interest) and retention. We also track intervention attendance and intervention adherence (completion of goal-setting homework and PA challenges) during weekly sessions. Participants in the intervention group rate satisfaction (enjoyment, helpfulness) during brief mid-point

Table 3
Connmigo assessments.

Family Systems Theory Communication [M&D] ^[58]	Parent-Adolescent communication ($\alpha = 0.78-0.87$)
PA Parenting Strategies [M&D] ^[59]	PA Parenting Practices (Limit setting, monitoring, and reinforcement ($\alpha = 0.81-0.82$)) and PA Parental Support (Non-directive and autonomy support, guided choice, rewards, supportive expectation, facilitation, and restriction of inside PA ($\alpha = 0.80$))
PA Parenting Support from Father [M] ^[60,61]	Paternal support for children's PA (when father figure reported) ($r = 0.73-0.79$)
PA Expectations [D]	Child perception of parental support for PA and outcome expectations
Social Cognitive Theory	
PA Motivation [M&D] ^[62]	Physical and psychological condition, affiliation, appearance, and enjoyment ($\alpha = 0.78-0.82$)
PA Barriers [M&D] ^[63]	Perceived barriers, feelings, and behaviors toward PA
Social Support for Exercise ^d [M] ^[64]	Family and friend support for exercise behaviors
PA Self-Regulation ^d [M] ^[65]	Self-monitoring, goal setting, social support, reinforcement, time management, and relapse prevention of PA
PA Outcomes	
Accelerometer PA [M&D]	Device measured PA
Self-report PA [M&D] ^[63,66]	Average minutes of MVPA/week, weekday/end minutes of PA and activity levels. ($k = 0.67-0.73$)
Health Outcomes & PA correlates	
Sleep ^a [M&D] & Screen Time [M&D] ^[67]	Average weekday and weekend hours of sleep and screen time
Mental Health [M&D] ^[68]	Generalized anxiety ($\alpha = 0.92$); Depressive symptomology ($\alpha = 0.85$); and COVID-19 Trauma/distress caused by pandemic events ($\alpha = 0.76$)
BMI [M&D]	Self-report height and weight
Nutrition ^c [D] ^[69]	Intake of fruits and vegetables by daughter
Self-Esteem [D] ^[70]	Positive and negative feelings about oneself ($\alpha = 0.77$)
Socio Demographic factors	
Demographics ^b [M&D] ^[71,72]	General demographic information; Acculturation (language use, media, and ethnic social relations ($\alpha = 0.66-0.74$)); Pubertal Development [D]

Notes: Participants completed measures at baseline, 3, and 6 months except where annotated: a) Baseline and 6 months; b) Baseline only; c) Baseline and 3 months; d) 6 months only. [M] = Mother; [D] = Daughter.

questionnaires during the intervention sessions and as part of the M2 surveys.

Process evaluation was guided by the National Institute of Health (NIH) Behavioral Change Consortium (BCC) Treatment Fidelity Framework, specifically concentrating on the domains of *study design delivery*, *receipt*, and *enactment* [47]. Data are being used for both formative (i.e., to monitor and refine the program during implementation) and summative (i.e., to assess the extent to which intervention was implemented as planned) purposes [48]. Specifically, the process evaluation helps determine (1) what components of the intervention are effective, (2) the degree to which the intervention was delivered with fidelity, (3) for whom the intervention is effective, (4) under what circumstances the intervention is effective, and (5) what changes or modifications are needed to enhance program effectiveness.

Data collection of process evaluation measurement consists of both self-report and observational (i.e., in vivo and video recording) methods described below according to NIH BCC Treatment fidelity framework domains (Table 4).

2.5.4. Qualitative feasibility and acceptability data

We conduct post-intervention interviews via Zoom with mothers and daughters to further evaluate the feasibility and acceptability of the sessions, asking about specific program topics, content, and activities to help improve session content. The development of qualitative interview guides was informed by Intervention Mapping and the Appropriate Areas of Focus for Feasibility Studies frameworks [36,49,50]. Interviews last 30–60 min and participants are compensated \$20 (mothers) and \$15

Table 4
Process evaluation data collection according to NIH BCC treatment fidelity framework domains.

Sub-domain	Measure	Description
Delivery of Treatment <i>Dose Delivered</i>	Attendance	Attendance taken by facilitators at all sessions across all waves
	Fidelity	Adherence Checklist
Quality	Modified SOFIT-X	10-16 item instructor self-assessment for expected performed actions each PA & didactic session [73, 74]
	Intensity of PA	17-item rater observed evaluation of PA instruction [75]
Receipt of Treatment <i>Dose Received</i>	Self-report questionnaires and qualitative interviews	Research staff wear accelerometers during randomly selected PA session recordings to assess amount of MVPA
	Attendance	Participants report on helpfulness, usefulness, and relevance of the intervention content and activities.
Participant Responsiveness (i.e., interest and satisfaction)	Self-report questionnaires and qualitative interviews	Calculated following completion of each wave of intervention participants, evaluated in relation to dose delivered.
	Self-report questionnaires and qualitative interviews	Participants rate their level of interest and satisfaction with intervention components such as facilitators, content, and group connections
Enactment of Treatment Skills <i>Performance of Intervention Skills</i>	Homework completion	Participants rate their level of interest and satisfaction with intervention components such as facilitators, content, and group connections
	Self-report surveys post-intervention	Self-report (Zoom poll) each session assessing completion of homework; submission of photos doing weekly PA
		Participants report level of confidence to perform and sustain intervention skills post-intervention

1 System for Observing Fitness Instruction Time in Group Exercise Classes.

(daughters). Data is analyzed using Rapid Qualitative methods [51].

2.6. Analysis plan

2.6.1. Analysis of outcomes (quantitative and qualitative)

Acceptability and feasibility. Qualitative data collected from post-intervention interviews with mothers and daughters help inform the optimization of *Connmigo*. Participants randomized to the intervention condition are invited to participate in one-on-one interviews to provide input on program components (topics, activities, kinds of PA, etc.) and logistics (session length, number of sessions, format, etc.) that appeal or do not appeal to participants. Data collected from the interviews are analyzed using rapid assessment methods [51] to make real-time adaptations between each wave and be responsive to participant needs.

Preliminary impact of program on PA. Quantitative data from surveys will provide preliminary evidence of the intervention's impact on primary (daughters' device-based PA) and secondary outcomes. The sample size is based on a comparison between the two groups across the post-intervention measurement at M2 as a vector of repeated measures on the primary outcome of the number of minutes/day of MVPA. Intended effect size is based on our review of studies, CDC guidelines of 420 min/week (60 min of PA/day every day) as well as staying within the guidelines suggested by Cohen that standardized effect sizes of 0.3–0.5 are considered small to medium in size, and these values have been recommended in the absence of previous effect size estimates for power calculations for future full-scale trials [52].

We will review data for completeness and accuracy prior to analyses. Preliminary data screening and cleaning will require examination of the data distributions for normality and missing data patterns at both the univariate and multivariate levels. Once completed, we will use multi-level regression modeling as the primary statistical model due to the nested structure of the data: repeated measures (time) [level-1] nested within dyads [level-2]. In the context of this design, time and dyad are crossed, not nested, and thus a 2-level model is appropriate. As the dyads are considered distinguishable as a daughter-mother pair, this design is also reciprocal as both members of the dyad will have both predictor and outcome variable scores. In the context of the multilevel models, actor and partner effects (as separate predictor variables) can be modeled simultaneously so that the bidirectional influence of the relationships of interest can be accounted for. Using this standard design over time, the dyadic data analytic approach will follow the recommendations of Kenny and Kashy, Brown et al. and the Prevention Science and Methodology Group for randomized field trials [53,54].

Analyses will include the between-subjects factor of the treatment group and the within-subjects factor of time. The cross-level group-by-time interaction effect will be of primary interest. If a given interaction is found to be statistically significant, we will perform follow-up analyses to determine the nature of the differential change between treatment conditions and will follow the procedures outlined by Preacher et al. [55]. Assessment of outcomes will follow the intention-to-treat principle. We will evaluate BMI, age, and pubertal development as potential covariates in these models. We will use this multilevel, dyadic approach to evaluate our research questions.

3. Discussion

The study addresses the important topic of increasing PA in Latinas, who are inactive, placing them at high risk of associated health consequences. We investigate the feasibility, acceptability, and impact of a 12-week intervention to promote PA in preadolescent Latina girls, using a mother-daughter intervention that is delivered via Zoom. Mothers and daughters attended 90-min weekly sessions rooted in Social Cognitive Theory and Family Systems Theory to promote PA [17,21].

This study addresses several important research gaps. Few studies have examined the impact of a PA intervention on mother-daughter dyads, and to our knowledge, only one study has evaluated the impact

of a mother-daughter PA intervention on preadolescent Latinas [33]. A benefit of targeting parent-child dyads is that each member of the dyad can support the other member's behavior changes promoted by the program. For example, mothers can encourage their daughters to engage in PA, and their daughters can support mothers' efforts to be active. Another important and innovative aspect of the *Connmigo* intervention is that it targets an important developmental period where girls are developing lifelong habits. Prior intervention research has focused on promoting PA among children and adults. The curriculum of *Connmigo* includes topics that have not traditionally been included in PA interventions. Topics like enhancing family communication, developing healthy coping skills, and managing stress are topics of great interest to mothers and complement topics like goal setting for and monitoring PA.

The *Connmigo* intervention is implemented via zoom due to COVID-19 pandemic restrictions. Although the original proposal was for in-person delivery, the online program has several advantages. Online delivery offers mothers and their daughters more flexibility to participate (e.g., the opportunity to make dinner immediately after participating, the ability to join calls from any location, etc.), and decreases barriers to access like transportation and travel time. Because online health programs can reach a greater proportion of the eligible population, *Connmigo* has the potential to be more scalable. Indeed, lack of access to safe and convenient spaces for PA may contribute to racial and ethnic disparities in PA – and online programs can overcome some of these barriers.

Our trial has limitations that warrant discussion. As a small-scale pilot study our trial had a moderate sample size, which may limit some analyses. Nevertheless, our team calculated the sample size based on the primary outcome (physical activity) and found 90 mother-daughter dyads to be sufficient to detect a true effect with 80% power. In addition, we included individuals with reliable internet access in program activities which could skew the sample to individuals with relatively high income and education levels; While the 2020 US Census reports that 93% of families in San Diego county have internet access, but this number was higher during the COVID-19 pandemic because many schools provided internet access and devices to families who needed them for remote school [56]. Despite these limitations, there are several strengths worth noting. We assess PA (our primary outcome) using self-report PA and gold standard methods – the accelerometer. Findings from a systematic review that examine the impact of PA interventions on mother-daughter dyads show that few used rigorous device-based PA data [57]. Objective device-based methods of assessing PA complement those collected through self-report methods.

4. Summary

This study addresses an important research gap and examines the impact and potential mechanisms of change of a mother-daughter intervention on daughters' PA in Latinas. In addition, we examine the bidirectional influence of mother-daughter PA, parenting regarding PA, and mother-daughter communication. Following completion of this study, we will conduct a large randomized trial that builds on the *Connmigo* study where we will be able to test the intervention on a larger scale and address more research questions including mediators (e.g., do girls increase in PA explain mothers' increase PA), moderators (e.g., do acculturated children influence mothers' PA more than less acculturated children), etc. We will also examine ways to adapt the intervention to different community settings like schools and YMCAs. The program can add value and complement existing programs in different community settings. For example, many YMCA's have PA programs but may benefit from programs that directly engage parents by providing parenting skills that would support parents' efforts in promoting PA. Another possibility would be to add a program in an after school care program among schools to engage parents and promote better socio-emotional health among children. Given the number of schools and YMCA's available in the US, the *Connmigo* program could be scalable. The ultimate goal is to address disparities in PA and make culturally sensitive programs

accessible and supportive of PA.

CRedit author statement

Elva M. Arredondo: Conceptualization, Methodology, Implementation, Writing, Reviewing. **Jennifer Schneider:** Conceptualization, Implementation, Writing, Reviewing. **Marisa Torres-Ruiz:** Conceptualization, Implementation, Supervision, Writing, Reviewing. **Victoria Telles,** Conceptualization, Implementation, Writing, Reviewing. **Katie Thralls-Butte:** Implementation, Writing, Reviewing. **Scott Roesch:** Conceptualization, Writing, Reviewing. **Michelle West:** Implementation, Writing, Reviewing. **Miriam Maldonado:** Implementation, Writing, Reviewing. **Kathleen Gallagher,** Implementation, Reviewing. **Guadalupe X. Ayala,** Conceptualization, Reviewing. **Tom Baranowski,** Conceptualization, Reviewing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

This work is conducted with support from an NIH/NICHD, R21HD100776 and NIH/NIMHD U54 U54 MD012397) and financial contributions from the College of Health and Human Services.

References

- Patterson, E. McNamara, M. Tainio, T.H. de Sa, A.D. Smith, S.J. Sharp, P. Edwards, J. Woodcock, S. Brage, K. Wijndaele, Sedentary behaviour and risk of all-cause, cardiovascular and cancer mortality, and incident type 2 diabetes: a systematic review and dose response meta-analysis, *Eur. J. Epidemiol.* 33 (9) (2018) 811–829.
- Á. Denche-Zamorano, J.M. Franco-García, J. Carlos-Vivas, M. Mendoza-Muñoz, D. Pereira-Payo, R. Pastor-Cisneros, E. Merellano-Navarro, J.C. Adsur, Increased risks of mental disorders: youth with inactive physical activity, *Healthcare* 10 (2) (2022).
- I.M. Lee, E.J. Shiroma, F. Lobelo, P. Puska, S.N. Blair, P.T. Katzmarzyk, Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy, *Lancet* 380 (9838) (2012) 219–229.
- C. Ozemek, C.J. Lavie, Ø. Rognum, Global physical activity levels - need for intervention, *Prog. Cardiovasc. Dis.* 62 (2) (2019) 102–107.
- U.S.D.o.H.a.H. Services, Physical Activity Guidelines for Americans, second ed., U.S. Department of Health and Human Services, Washington, DC, 2018.
- L. Kann, T. McManus, W.A. Harris, S.L. Shanklin, K.H. Flint, B. Queen, R. Lowry, D. Chyen, L. Whittle, J. Thornton, C. Lim, D. Bradford, Y. Yamakawa, M. Leon, N. Brener, K.A. Ethier, Youth risk behavior surveillance - United States, 2017, morbidity and mortality weekly report, *Surveillance Summaries* 67 (8) (2018) 1–114.
- S.Y. Kimm, N.W. Glynn, A.M. Kriska, S.L. Fitzgerald, D.J. Aaron, S.L. Similo, R. P. McMahon, B.A. Barton, Longitudinal changes in physical activity in a biracial cohort during adolescence, *Med. Sci. Sports Exerc.* 32 (8) (2000) 1445–1454.
- A.J. Milat, A.E. Bauman, S. Redman, N. Curac, Public health research outputs from efficacy to dissemination: a bibliometric analysis, *BMC Publ. Health* 11 (2011), 934–934.
- W.B. Strong, R.M. Malina, C.J.R. Blimkie, S.R. Daniels, R.K. Dishman, B. Gutin, A. C. Hergenroeder, A. Must, P.A. Nixon, J.M. Pivarnik, T. Rowland, S. Trost, F. Trudeau, Evidence based physical activity for school-age youth, *J. Pediatr.* 146 (6) (2005) 732–737.
- J.A. Kahn, B. Huang, M.W. Gillman, A.E. Field, S.B. Austin, G.A. Colditz, A. L. Frazier, Patterns and determinants of physical activity in U.S. adolescents, *J. Adolesc. Health: Official Publication Of The Society For Adolescent Medicine* 42 (4) (2008) 369–377.
- R.K. Dishman, R.W. Motl, R. Saunders, G. Felton, D.S. Ward, M. Dowda, R.R. Pate, Enjoyment mediates effects of a school-based physical-activity intervention, *Med. Sci. Sports Exerc.* 37 (3) (2005) 478–487.
- H.E. Brown, A.J. Atkin, J. Panter, Family-based interventions to increase physical activity in children: a meta-analysis and realist synthesis protocol, *BMJ Open* 4 (2014), e005439.
- N. Pearson, R. Braithwaite, S.J. Biddle, The effectiveness of interventions to increase physical activity among adolescent girls: a meta-analysis, *Academic pediatrics* 15 (1) (2015) 9–18.
- S.E. Ross, L.A. Francis, Physical activity perceptions, context, barriers, and facilitators from a Hispanic child's perspective, *Int. J. Qual. Stud. Health Well-Being* 11 (2016), 31949.
- N. Mathew Joseph, P. Ramaswamy, J. Wang, Cultural factors associated with physical activity among U.S. adults: an integrative review, *Appl. Nurs. Res. : ANR* 42 (2018) 98–110.
- D.J. Biederman, T.R. Nichols, D.D. Durham, Maternal navigational strategies: examining mother-daughter dyads in adolescent families of color, *J. Fam. Nurs.* 16 (4) (2010) 394–421.
- C. Broderick, *Understanding Family Processes*, Sage Publications, Thousand Oaks, A, 1993.
- E.M. Arredondo, J.P. Elder, G.X. Ayala, N. Campbell, B. Baquero, S. Duerksen, Is parenting style related to children's healthy eating and physical activity in Latino families? *Health Educ. Res.* 21 (6) (2006) 862–871.
- A.T. Barnes, R.C. Plotnikoff, C.E. Collins, P.J. Morgan, Feasibility and preliminary efficacy of the MADE4Life program: a pilot randomized controlled trial, *J. Phys. Activ. Health* 12 (10) (2015) 1378–1393.
- I.J. Ornelas, K.M. Perreira, G.X. Ayala, Parental influences on adolescent physical activity: a longitudinal study, *Int. J. Behav. Nutr. Phys. Activ.* 4 (2007), 3–3.
- A. Bandura, *Social Learning Theory*, Social Learning Theory, Prentice-Hall, 1977, pp. viii–247, vols. iii, 247.
- D.K. Wilson, A.M. Sweeney, H. Kitzman-Ulrich, H. Gause, S.M. St George, Promoting social nurturance and positive social environments to reduce obesity in high-risk youth, *Clin. Child Fam. Psychol. Rev.* 20 (1) (2017) 64–77.
- K. Joyal-Desmarais, R.L. Lenne, M.E. Panos, C.O. Huelsnitz, R.E. Jones, L.A. Auster-Gussman, W.F. Johnson, J.A. Simpson, A.J. Rothman, Interpersonal Effects of Parents and Adolescents on Each Other's Health Behaviours: a Dyadic Extension of the Theory of Planned Behaviour, *Psychology & health*, 2019, pp. 1–21.
- R.L. Lenne, K. Joyal-Desmarais, R.E. Jones, C.O. Huelsnitz, M.E. Panos, L.A. Auster-Gussman, W.F. Johnson, A.J. Rothman, J.A. Simpson, Parenting styles moderate how parent and adolescent beliefs shape each other's eating and physical activity: dyadic evidence from a cross-sectional, U.S. National Survey, *J. Exp. Soc. Psychol.* 81 (2019) 76–84.
- K. de la Haye, H.D. de Heer, A.V. Wilkinson, L.M. Koehly, Predictors of parent-child relationships that support physical activity in Mexican-American families, *J. Behav. Med.* 37 (2) (2014) 234–244.
- L.C. Masse, L.A. Lytle, Advancing knowledge of parent-child dyadic relationships about multiple cancer preventive health behaviors: the national cancer Institute family life, activity, sun, health, and eating (FLASHE) study, *Am. J. Prev. Med.* 52 (6) (2017) 833–835.
- R.E. Rhodes, C. Lim, Promoting parent and child physical activity together: elicitation of potential intervention targets and preferences, *Health Educ. Behav. : the official publication of the Society for Public Health Education* 45 (1) (2018) 112–123.
- A.T. Barnes, M.D. Young, E.M. Murtagh, C.E. Collins, R.C. Plotnikoff, P.J. Morgan, Effectiveness of mother and daughter interventions targeting physical activity, fitness, nutrition and adiposity: a systematic review, *Prev. Med.* 111 (2018) 55–66.
- L.C. Masse, T.M. O'Connor, A.W. Tu, S.O. Hughes, M.R. Beauchamp, T. Baranowski, Conceptualizing physical activity parenting practices using expert informed concept mapping analysis, *BMC Publ. Health* 17 (1) (2017) 574.
- S. Alhassan, O. Nwaokemele, C.J. Greever, S. Burkart, M. Ahmadi, C.W. St Laurent, D.J. Barr-Anderson, Effect of a culturally-tailored mother-daughter physical activity intervention on pre-adolescent African-American girls' physical activity levels, *Preventive medicine reports* 11 (2018) 7–14.
- L.B. Ransdell, L. Robertson, L. Ornes, L. Moyer-Mileur, Generations Exercising Together to Improve Fitness (GET FIT): a pilot study designed to increase physical activity and improve health-related fitness in three generations of women, *Women Health* 40 (3) (2004) 77–94.
- N. Olvera, J.A. Bush, S.V. Sharma, B.B. Knox, R.L. Scherer, N.F. Butte, BOUNCE: a community-based mother-daughter healthy lifestyle intervention for low-income Latino families, *Obesity* 18 (2010), 19307381. S102-S104.
- N.N. Olvera, B. Knox, R. Scherer, G. Maldonado, S.V. Sharma, L. Alastuey, J. A. Bush, A healthy lifestyle program for Latino daughters and mothers: the BOUNCE overview and process evaluation, *Am. J. Health Educ.* 39 (5) (2008) 283–295.
- H. Kitzman-Ulrich, D.K. Wilson, S.M. St George, H. Lawman, M. Segal, A. Fairchild, The integration of a family systems approach for understanding youth obesity, physical activity, and dietary programs, *Clin. Child Fam. Psychol. Rev.* 13 (3) (2010) 231–253.
- E. Valdivieso-Mora, C.L. Peet, M. Garnier-Villarreal, M. Salazar-Villanea, D. K. Johnson, A systematic review of the relationship between familism and mental health outcomes in Latino population, *Front. Psychol.* 7 (2016) 1632.
- D.J. Bowen, M. Kreuter, B. Spring, L. Cofta-Woerpel, L. Linnan, D. Weiner, S. Bakken, C.P. Kaplan, L. Squiers, C. Fabrizio, M. Fernandez, How we design feasibility studies, *Am. J. Prev. Med.* 36 (5) (2009) 452–457.
- A. Ramsetty, C. Adams, Impact of the digital divide in the age of COVID-19, *J. Am. Med. Inf. Assoc.* 27 (7) (2020) 1147–1148.
- D.E.R. Warburton, V.K. Jamnik, S.S.D. Bredin, N. Gledhill, The physical activity readiness questionnaire for everyone (PAR-Q+) and electronic physical activity readiness medical examination (ePARmed-X+), *The Health & Fitness Journal of Canada* 4 (2) (2011) 3–17.
- Youth physical activity readiness questionnaire (PAR-Q). <https://www.libertyathletic.net/Files/Library/PARQYOUTH06-18.PDF>. 2020, 2020.
- E.M. Arredondo, M. Morello, C. Holub, J. Haughton, Feasibility and preliminary findings of a church-based mother-daughter pilot study promoting physical activity among young Latinas, *Fam. Community Health* 37 (1) (2014) 6–18.
- E. Waters, A. de Silva-Sanigorski, B.J. Hall, T. Brown, K.J. Campbell, Y. Gao, R. Armstrong, L. Prosser, C.D. Summerbell, Interventions for preventing obesity in children, *Cochrane Database Syst. Rev.* 12 (2011), Cd001871.

- [42] T.M. O'Connor, R. Jago, T. Baranowski, Engaging parents to increase youth physical activity a systematic review, *Am. J. Prev. Med.* 37 (2) (2009) 141–149.
- [43] A. Timperio, J. Salmon, K. Ball, Evidence-based strategies to promote physical activity among children, adolescents and young adults: review and update, *J. Sci. Med. Sport* 7 (1 Suppl) (2004) 20–29.
- [44] M.L. Smith, N.K. Durrett, M. Bowie, A. Berg, B.A. McCullick, A.C. LoPilato, D. Murray, Individual and group-based engagement in an online physical activity monitoring program in Georgia, *Prev. Chronic Dis.* 15 (2018) E72.
- [45] T. Rose, M. Barker, C. Maria Jacob, L. Morrison, W. Lawrence, S. Strömmer, C. Vogel, K. Woods-Townsend, D. Farrell, H. Inskip, J. Baird, A systematic review of digital interventions for improving the diet and physical activity behaviors of adolescents, *J. Adolesc. Health* 61 (6) (2017) 669–677.
- [46] S. Michie, M. Richardson, M. Johnston, C. Abraham, J. Francis, W. Hardeman, M. P. Eccles, J. Cane, C.E. Wood, The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions, *Ann. Behav. Med.* : a publication of the Society of Behavioral Medicine 46 (1) (2013) 81–95.
- [47] B. Borrelli, The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials, *J. Publ. Health Dent.* 71 (s1) (2011) S52–S63.
- [48] R.E. Saunders, Martin, Praphul Joshi, Developing a process-evaluation plan for assessing health promotion program implementation: a how-to guide, *Health Promot. Pract.* 6 (2) (2005) 134–147.
- [49] L. Highfield, M.A. Hartman, P.D. Mullen, S.A. Rodriguez, M.E. Fernandez, L. K. Bartholomew, Intervention mapping to adapt evidence-based interventions for use in practice: increasing mammography among african American women, *BioMed Res. Int.* 2015 (2015), 160103.
- [50] S.A. Rodriguez, A.M. Roncancio, L.S. Savas, D.M. Lopez, S.W. Vernon, M. E. Fernandez, Using intervention mapping to develop and adapt two educational interventions for parents to increase HPV vaccination among hispanic adolescents, *Front. Public Health* 6 (2018) 164.
- [51] A.B. Hamilton, E.P. Finley, Qualitative methods in implementation research: an introduction, *Psychiatr. Res.* 280 (2019), 112516.
- [52] A.L. Whitehead, S.A. Julious, C.L. Cooper, M.J. Campbell, Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable, *Stat. Methods Med. Res.* 25 (3) (2016) 1057–1073.
- [53] C.H. Brown, W. Wang, S.G. Kellam, B.O. Muthén, H. Petras, P. Toyinbo, J. Poduska, N. Ialongo, P.A. Wyman, P. Chamberlain, Z. Sloboda, D.P. MacKinnon, A. Windham, P.S.a.M. Group, Methods for testing theory and evaluating impact in randomized field trials: intent-to-treat analyses for integrating the perspectives of person, place, and time, *Drug Alcohol Depend.* 95 (Suppl 1) (2008) S74–S104.
- [54] D.A. Kenny, D.A. Kashy, *Dyadic Data Analysis Using Multilevel Modeling*, Handbook for Advanced Multilevel Analysis, Routledge/Taylor & Francis Group, New York, NY, US, 2011, pp. 335–370.
- [55] K.J. Preacher, P.J. Curran, D.J. Bauer, Computational tools for probing interactions in multiple linear regression, multilevel modeling, and latent curve analysis, *J. Educ. Behav. Stat.* 31 (4) (2006) 437–448.
- [56] U.S. Census, Bureau (n.d.), 2022.
- [57] C. Brennan, G. O'Donoghue, A.M. Hall, A. Keogh, J. Matthews, A systematic review of the intervention characteristics, and behavior change theory and techniques used in mother-daughter interventions targeting physical activity, *Prev. Med.* 153 (2021), 106764.