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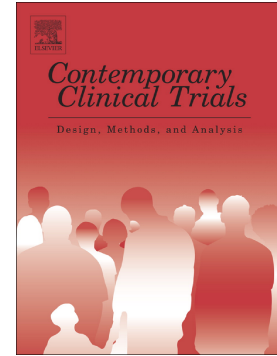
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Designing a Virtual Mental Health Consultation Program to Support and Strengthen Childcare Centers Impacted by COVID-19: A Randomized Controlled Trial Protocol

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Abstract

Background: The COVID-19 pandemic has had negative psychosocial impacts on young children; teachers in childcare centers continue to be overwhelmed by how to address the downstream psychological effects children are experiencing. This randomized controlled trial

will study the role of a community-based, childcare center-support system in improving resilience and mitigating the long-term impacts of COVID-19 on children's development.

Methods: This study will be modeled on a successful Early Childhood Mental Health Consultation (ECMHC) intervention which utilizes mental health consultants to deliver a Jump Start+: COVID 19 Support (JS+CS) virtual toolkit to childcare centers in Miami-Dade County via a Kubi robot. The toolkit comprises four strength-based strategies likely to be effective in improving resiliency following disasters: Safety Planning, Effective Communication, Adult Self-Care, and Trauma-Informed Behavior Support. Our first aim will utilize a cluster randomized trial to examine the effectiveness of JS+CS on improving the psychosocial functioning of young children, as compared to an obesity prevention intervention control group. Children will be followed at 6, 12, 18, and 24 months. The second aim will examine the mechanisms that contribute to effective uptake by teachers of the JS+CS support strategies on child outcomes. The third aim will explore implementation barriers/facilitators as well as potential societal contextual factors (e.g., vaccine uptake) to help centers serving disproportionately affected minority communities recover from and prepare for future crises.

Conclusion: This design will inform the refinement and scaling of JS+CS and generalize impacts to other childcare center interventions in the context of disasters.

ClinicalTrials.gov Identifier: NCT05445518

Keywords: early childhood, childcare center, COVID-19, virtual consultation, resiliency

1. Introduction

Childcare centers are essential businesses that have been negatively impacted by the COVID-19 pandemic and other public health crises, with downstream negative effects on teachers, children, and families; yet little is known about effective public health interventions that can address centers' pressing short- and long-term needs.

The pandemic has had devastating impacts on children's psychosocial health, ranging from long-term social isolation to heightened family stressors.[1] Children as young as two are experiencing anxiety, irritability, anger, and stress.[2,3] The incidence and severity of behavior problems are increasing in children with and without a prior history of behavior problems,[4-6] and once through the acute phase of the pandemic, "sleeper" effects on children's mental health are predicted.[7] Early data found that children ages 2-5 years had elevated behavior problems, which were higher in parents reporting lower-income and more COVID-19 stress.[8,9] School closures and cumulative exposure to adverse events can negatively impact social-emotional, behavioral, and cognitive development during the critical period (0-5 years) when the foundation of learning is built.[10-14] Enrollment in high-quality childcare centers with nurturing caregivers can buffer these negative effects by building resiliency and by strengthening self-regulation and executive functioning skills.[15-17] Unfortunately, our Childcare Worker Job Stress Inventory showed that early childhood teachers felt overwhelmed with additional burdens of maintaining a safe environment during the pandemic while delivering quality classroom practices.[18,19] The result has been staff turnover and poorly functioning classrooms.[20,21] Therefore, it is essential to intervene at multiple levels to increase support for teachers, build child resilience, and foster a center environment anchored in policies that promote positive growth during stressful times.

COVID-19 has also provided a strategic opportunity to deliver virtual intervention support to childcare centers. Safety standards at childcare centers have changed, including

limiting visitors, even parents or consultants. With decreased rates of infectious disease

transmission, including flu, many centers are maintaining these visitation restrictions and prefer

teleconsultations. In addition to reducing disease transmission, virtual supports such as mental

health teleconsultations reduce travel time and driving fatigue for consultants. One novel way to

increase service accessibility and feasibility is by using a Kubi, an affordable telepresence robot

that holds a tablet that can connect to Zoom or other video conferencing software. The remote

user connects to the tablet using the Kubi Connect App, which pairs the tablet to the telepresence

robot via Bluetooth. Teleconsultation via the Kubi is superior to other methods because it allows

for a broader rotating view to watch and listen as teachers practice strategies (teacher-child

interactions), and it aids in observations by providing a more real-life, face-to-face experience of

how the classroom and center functions. In order to reduce classroom distractions by the Kubi

during remote teleconsultations, the video camera of the remote consultant is turned off. While

preliminary evidence supports the use of Kubi telepresence robots in hard-to-access schools,

literature assessing their use in childcare settings is limited.[22,23]

In response to the urgent need to support childcare centers during the pandemic, our team

was one of the first in the country to develop a mental health toolkit, Jump Start+: COVID

Support (JS+CS), to prepare them to handle public health crises.[18] The program uses the JS+CS

toolkit so that mental health consultants (MHCs), who are considered "trusted messengers,"

provide centers with psychosocial coping strategies to boost resilience and easy-to-access safety

information to address infection-related concerns. The toolkit is organized around four program

pillars: two are psychosocial (Self-Care, Trauma-Informed Behavior Support) and two are

safety-related (Safety, Communication). Importantly, and given evolving safety standards that

limited consultant visitation, we quickly pivoted to providing JS+CS consultations virtually so that we could continue to support teachers during the pandemic.

While our preliminary data show that JS+CS helps reduce teacher stress and improve centers' capacity to implement emergency preparedness guidelines, the short- and longer-term impact of JS+CS on child, teacher, and center outcomes has not yet been rigorously tested.[19] As such, there are three aims of this study. Aim 1 works to improve the psychosocial functioning of children during and after COVID-19. Specifically, we hypothesize that relative to the control group, children in the intervention group will exhibit improved psychosocial outcomes as demonstrated by reduced behavior problems and improved resiliency (executive functioning and prosocial behaviors). Aim 2 works to improve teacher psychosocial functioning, so that teachers can be more resilient and provide better quality classroom practices. We hypothesize that JS+CS will improve teacher psychosocial functioning as evidenced by changes in attitudes (self-efficacy), beliefs (stress), and classroom practices (teacher-child interactions). Aim 3 will help strengthen the capacity of childcare centers to improve physical safety and psychosocial support standards by understanding barriers and facilitators to effectively implementing JS+CS. We hypothesize that centers implementing JS+CS policies will improve the physical safety and psychosocial practices that lead to better quality childcare.

1.1 Theoretical Model

The Early Childhood Mental Health Consultation (ECMHC) theory of change serves as the conceptual framework (Figure 1). ECMHC, through mental health consultants, has proven effective in addressing young children's behavioral health by building the capacity of childcare teachers to develop the attitudes and skills necessary to effectively support the development of resilience in young children.[24-27] The JS+CS Toolkit is organized into four pillars that work

together to build resilience by improving psychosocial coping through *Self-Care and Trauma-informed Behavior Supports* and disaster recovery practices by improving *Safety and Communication practices*. The pillars are based on Caring for Our Children–National Health and Safety Standards[28], supplemented with CDC COVID-19 guidelines for Childcare Centers[29] and other evidenced-based practices.[30,31]
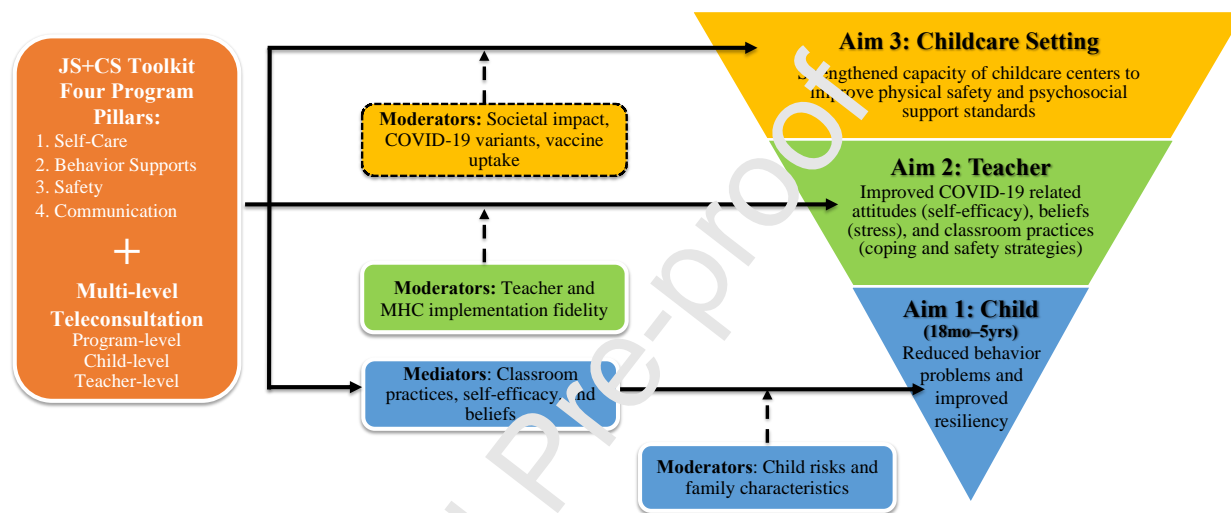
Figure 1. Program Model Overview

The JS+CS toolkit is delivered by Mental Health Consultants (MHCs). They provide toolkit implementation strategies at three levels to improve child psychosocial functioning (Aim 1), teacher psychosocial functioning and classroom practices (Aim 2), and the center's capacity to maintain safety and psychosocial support (Aim 3). MHCs are master's level clinicians trained in the ECMHC framework which uses the "consultative stance" to build relationships.[32,33] The multimedia toolkit provides strategies on how to implement the program pillars to achieve outcomes.

Overall, we posit that child psychosocial functioning (prosocial and reduced internalizing/ externalizing) and resiliency (children's self-regulation) will improve by working with teachers

to improve their teaching practices (e.g., use of trauma-focused behavior management), teacher's increased self-efficacy when facing challenging behaviors (attitudes), and their beliefs (support from center directors).[18,20,34,35] Table 1 provides examples of strategies implemented that are hypothesized to lead to change at 3 levels: center level, teacher level, and child level. Considering response burden and power, specifically, we will evaluate family moderating factors including stress, low income, vaccine uptake/confidence, and parent safety practices outside of school[36,37] based on the Halfon et al. risk model.[38]

Table 1: Toolkit Pillars, Goals, and Example Strategies			
Pillar 1: *Physical & Psychological Safety*	**Pillar 2:** *Communication*	**Pillar 3:** *Self-Care*	**Pillar 4:** *Trauma-informed Behavior Support*
Center Level Goal: Comply with CDC guidelines *Strategy: Refine policies in accordance with CDC's disaster recovery guidelines and share JS+CS COVID cartoon videos with parents and children* *Measure: Health Environment Rating Scale – Program*	**Center Level Goal**: Develop strong partnerships with teachers and parents *Strategy: Director/teacher collaborative goal setting and supporting staff with parent communication* *Measure: Key Informant Interviews*	**Center Level Goal**: Promote staff resilience *Strategy: Develop wellness policies, resiliency planning to identify self-care practices, staff social support, and scheduled stress check-ins with teachers* *Measure: Health Environment Rating Scale – Program and Key Informant interview*	**Center Level Goal**: Promote center-wide policy on positive behaviors and transform negative behaviors *Strategy: Ongoing staff continuing education on trauma-informed classroom management strategies* *Measure: Health Environment Rating Scale – Program*
Teacher Level Goal: Be a healthy role model *Strategy: Practice COVID-19 related safety guidelines and model self-regulation to promote safety and security within the classroom*	**Teacher Level Goal:** Develop strong partnerships with families *Strategy: Hold ongoing staff and parent meetings to review updated COVID safety procedures.*	**Teacher Level Goal:** Plan ahead for stress management *Strategy: Practice daily mindfulness and additional verbal and non-verbal strategies to model self-regulation techniques for children and self.*	**Teacher Level Goal:** Promote positive classroom climate *Strategy: Use 1,2,3 calming and positive reinforcement with specific praise for child prosocial behaviors and engagement*

Measure: Health Environment Rating Scale – Classroom	*Measure: Child Care Worker Job Stress Inventory*	*Measure: Child Care Worker Job Stress Inventory*	*Measure: Health Environment Rating Scale – Classroom*
Child Level Goal: Ensure children are emotionally supported through grief and stress *Strategy: Use social stories to teach children about overcoming challenges* *Measure: Devereux Early Childhood Assessment*	**Child Level Goal:** Promote positive behaviors at home and school *Strategy: Establish school-home communication notes and shared reward-based system to support positive child behaviors)* *Measure: Child Behavior Checklist*	**Child Level Goal:** Promote children's sense of self and attachment security *Strategy: Use I Love You Rituals (Becky Bailey) for expressing anger and need for attention* *Measure: Devereux Early Childhood Assessment*	**Child Level Goal:** Promote children's self-control/regulation and initiative *Strategy: Use trauma-informed practices such as "calm down box" with feather, scents etc. to teach children breathing and relaxation* *Measure: Strengths and Difficulties Questionnaire*

2. Methods

2.1 Participants and Study Sampling

Implementation is guided by Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework.[39] RE-AIM uses strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings. The RE-AIM framework has been used in our pilot work and full details can be found elsewhere.[40] We will use a Type 1 implementation-effectiveness approach to identify implementation facilitators and barriers that will offer critical insights on the uptake of COVID-19 interventions in real time.[41] This Type 1 approach is superior to other effectiveness studies because it will inform the refinement and scaling up of JS+CS so that results can be rapidly used to support other childcare centers in the context of disasters.[41]

Within the Type 1 hybrid implementation-effectiveness design[42], we will utilize a cluster-randomized trial to assess effectiveness and collect data on observed barriers and facilitators to better understand the uptake of implementation for JS+CS. As the intervention is multi-level and center-wide, we will randomly assign centers (N=24) to one of two groups (intervention or

attention control). In cluster-randomized trails, clusters (i.e., childcare centers) rather than individuals are randomized to intervention or control groups and outcomes are measured on individuals within those clusters. The intervention group will receive the JS+CS program (n=12). The attention control group (n=12) is an active, time matched group that will receive the HC2 obesity prevention program, a program unrelated to JS+CS.[43,44]

Randomization will be balanced via block randomization for ethnicity with half the centers in each group serving predominantly Hispanic families and the other half non-Hispanic Black families, allowing for ethnic group comparisons within balance in each group. In order to have adequate power for our multi-level nesting design[45] (described below), we will recruit 720 children/families (360 intervention, 360 control), 120 teachers/classrooms (60 intervention, 60 control), and 24 directors (12 each group). To obtain unbiased medium-level effect sizes, previous studies have recommended including above 20 clusters (i.e., centers) and above 5-6 individuals (i.e., children).[46,47] Thus, we are being conservative in estimating 24 centers, with 120 classrooms and 6 children in each. All centers will be part of the Quality Improvement System, a governing body which enrolls childcare centers and monitors the quality of services provided to 417 centers in the county. Center inclusion criteria: (1) have ≥ 50 children (≥ 30 of whom are 18 month-3 years old); (2) be located in the low-income census tract, with at least 50% of families receiving childcare subsidy; (3) serve at least 60% Hispanic or 60% Non-Hispanic Black families; (4) have directors and teachers who agree to participate; and (5) be a Quality Improvement System center with a star rating of 3 indicating average quality practices (range 1-5) and not previously enrolled in Jump Start.

2.2 Intervention Group

There are 3 steps to ensure that the toolkit is successful, sustainable, and implemented with fidelity. **STEP 1 Toolkit Implementation.** <u>Content</u>: The toolkit includes: (1) infographics with goals and myth-busting facts that pertain to intervention pillars; (2) how-to cartoon videos demonstrating resiliency-based coping strategies for teachers and directors; (3) cartoon videos directed at preschool children to assist in adherence to infectious disease control guidelines that are relevant post-pandemic (e.g., hand washing). To ensure our toolkit is up to date, our Scientific Advisory Committee meets monthly to review the latest CDC guidelines and propose toolkit changes. <u>Structure</u>: The Toolkit Action Plan is a standardized implementation protocol used by MHCs in each teleconsultation to 1) set the goal based on the pillar for the week, 2) provide strategies for achieving the goals using infographics and "how-to" videos located on our website, 3) have teachers practice strategies while MHCs provide real-time feedback. Six weeks are devoted to each pillar before moving on to the next (in the order of Self-Care, Behavior Support, Safety, Communication). <u>Dose</u>: MHCs provide 24 weeks of teleconsultations for 4 hours weekly per center, divided between directors and teachers. Center-level teleconsultations occur with the directors for 1 hour per week to build center-wide capacity by focusing on how they can implement that week's pillar policies into practice. Classroom-level teleconsultations occur in a small virtual group (2-3 teachers) for 1 hour per week, during "Break and Breathe", to provide teachers with goals/strategies to adopt pillars into their daily lives. Examples of goals/strategies include helping teachers develop a self-care plan to build resiliency (beliefs) and use coping strategies (self-efficacy) and collaborating/engaging with parents by posting cartoon videos with parent tips through a multimodal platform such as WhatsApp or Facebook (practices). Child-level teleconsultations occur for 2 hours each week (20 minutes individually

for each teacher) to focus on implementing the goals/strategies with the children (teacher practices). See Table 1. Telepresence robot integration: Each school will receive a Kubi Plus with Enhanced Audio telepresence robot that the MHCs will use to deliver the intervention. The robots, which are operated remotely by MHCs, are stationary devices that can tilt and pan around a classroom while video conferencing with individuals in the classroom. It has microphones and large speakers for group classroom sound. MHCs can use the audio to provide live classroom practice strategies and teacher feedback using a single Bluetooth earbud to minimize child distractions. Before initiating services, MHCs will train teachers on how to a) structure the environment for telepresence robot classroom consultation or observation sessions, b) initiate and end sessions, and 3) troubleshoot common problems.

STEP 2 Sustainability and Cultural and Linguistic Relevance. From the first teleconsultation, a sustainability plan is developed as part of the Action Plan. This includes the identification of a "Program Champion," a lead teacher (paid a $500 stipend/per annum) who pledges to support the center in maintaining toolkit strategies. In years 2 and 3, the MHCs will provide quarterly 2-hour refresher trainings (booster sessions) with all teachers and the Program Champion to help maintain their skill set in supporting center-wide implementation of toolkit pillars and policy standards. We use the 8 dimensions of the Ecological Validity Model to ensure that the toolkit has the necessary cultural and linguistic adaptations to reduce health disparities.[48] The Ecological Validity Model is the most widely used approach to culturally adapting interventions.[49] Specific cultural targeting strategies include peripheral, evidential, linguistic, constituent involving, and socio-cultural strategies.[50] As an example, all materials will be translated into Spanish (linguistic strategies) and will include photos of ethnic minorities

(peripheral strategies) and information about national and local prevalence data related to teacher

practices and children of ethnic minority groups (evidential strategies).

STEP 3 Monitoring Fidelity. Fidelity is based on Dane and Schneider's 5 components:

Adherence, Exposure, Participant Responsiveness, Quality of Delivery, and Program

Differentiation (described in Measures).[51]

2.3 Active Time-Matched Control Group

Centers randomized to the attention control will receive an existing obesity prevention

program, Healthy Caregivers-Healthy Children (HC2) by the MHCs. This program was fully

developed and implemented through federal funding by the PI and was empirically found to

improve obesity prevention practices within centers that were ethnically similar to this

study.[43,44,52] Control centers receive all the same pre- and post- measures and incentives as the

intervention arm to ensure retention. The same 3-step process will be followed for the control

group and intervention group.

2.4 Procedures

The study has been approved by University's Institutional Review Board and has been

registered with ClinicalTrials.gov number NCT05445518. We will use CONSORT guidelines'

extension for social and psychological intervention trials to report RCT enrollment and retention

data as well as to generate a participant flow diagram. We are recruiting, within the existing

childcare network, 24 childcare centers that serve low-income families from ethnic minority

backgrounds. Interested center directors will complete a readiness screener that assesses

eligibility. Eligible center directors who give informed consent will then complete the baseline

survey. Graduate-level research assistants (RAs) will be from commensurate ethnic minority

backgrounds and have experience working in their assigned area of the county (north and south).

Centers will be recruited and consented first, followed by teachers, and then families. A virtual

kick off with a "Meet and Greet the Robot" will occur weekly for the first 2 weeks for teachers

and then 2 weeks later for parents, during which the study will be explained by our program's

MHC. Participants giving verbal agreement are contacted by the RA based on their preference

(email or phone) to obtain consent and measures. Teacher self-reports, teacher ratings of

children, center director information, and parent ratings all will be collected by electronic

administration via REDCap with an option for oral administration of measures. The RAs will

utilize the Robot for classroom observational measures via live streaming to avoid video

recordings of children. All data will be entered into the REDCap system, a secure, web-based

application designed exclusively to support data capture for research studies. Measures will be

collected at 6-month intervals: baseline (T1), 6 months (T2), 12 months (T3), 18 months (T4),

and 24 months (T5). All the same measures will be administered at all five timepoints.

2.5 Measures

2.5.1 Aim 1

Given that the toolkit is designed to mitigate COVID-19's effects by improving

resilience, we are using a parent and teacher report measure, the Devereux Early Childhood

Assessment (DECA) to determine improvements to those child prosocial behaviors that are

linked to resilient behaviors in young children.[53,54] Internal consistency is adequate in a low-

income diverse English and Spanish speaking sample.[55] Children's externalizing and

internalizing measures will be assessed by parent and teacher report via the Strengths and

Difficulties Questionnaire. This is a primary outcome measure.

Caregiver life stress will be measured by the Everyday Stressors Index (ESI, moderator)

with good reliability, validity, and internal consistency in our samples (alpha= .98), and in other

studies including low-income families with young children.[56-59] **Family characteristics** (i.e., English proficiency, gender, race, ethnicity, country of birth, single parent status, primary language spoken in the home, employment, income level, and years of education) will be measured by our JS+CS demographic survey.[40] This is a secondary outcome measure.

Family COVID-19 precaution behaviors will be measured using a dichotomized checklist of caregiver reported behaviors that follow CDC recommendations and adult and child vaccine uptake and confidence (if emergency authorization is approved for 1–3-year-olds) measured by specific items from the NIH Rapid Acceleration of Diagnostics (RADx) COVID-19 Common Data Elements Survey.[60-62] According to ECMHC, child development outcomes are mediated by teachers' practices (measured by implementation of JS+CS strategies assessed through the Health Environment Rating Scale–Classroom (HERS-C) and teachers' self-efficacy and beliefs (both measured by the Childcare Worker Job Stress Inventory described below).[24-27]

2.5.2 Aim 2

Prior ECMHC and JS research suggests that improving classroom practices impacts child development.[25,40,63] **Classroom practices (psychosocial support safety strategies)** will be assessed through the Health Environment Rating Scale–Classroom (HERS-C) observation. This is a primary outcome measure. The HERS-C is a 30-minute observation developed by the investigators to align with core national standards including NAEYC and Caring for Our Children-3rd edition and has been used for the past 8 years.[28,31] It is comprised of 5 domains (safety, behavioral supports, communication, self-care, and nutrition/physical activity) and scored via a 7-point Likert scale. It is useful because 1) it maps on to each of the 4 JS+CS program pillars; 2) no other measures exist that align with ECMHC key program implementation factors; and 3) it includes Nutrition and Physical Activity domains that will be used to measure

expected changes in the control centers that are receiving the obesity prevention intervention.[64,65] Validity is demonstrated with positive associations with the Classroom Assessment Scoring System (CLASS (*r*'s ranging from .30-.60)). Adequate interrater agreement has been achieved in prior studies ($\geq$.80).

Teachers' attitudes (sense of self-efficacy related to managing stressors) and teacher's beliefs (job stress, coping, distress) will be measured by the Childcare Worker Job Stress Inventory, which assesses 3 domains of workplace stress, including job demands, resources, and control.[66] The domains have strong internal consistency and constructive validity and have been used effectively in our JS pilot and other ECMHC models with low-income children.[67] **This is a secondary outcome measure.**

Teacher and consultant fidelity variables will be included as moderators: 1) <u>Adherence Checklist</u>: coded on proportion of strategies that were delivered compared to the number prescribed in the Action Plan, 2) <u>Exposure Contact Log</u>: coded on the frequency and length of consultation sessions and total minutes spent viewing online toolkit, 3) <u>Quality of Delivery</u>: total score out of 100 on the Fidelity Form, 4) <u>Program Differentiation</u>: based on a dichotomous variable on the Fidelity Form to determine if intervention spillover occurred between JS+:CS and HC2, 5) <u>Responsiveness</u>: total score on the Usefulness and Ease of use domains of the Technology Acceptability Fast form.

Teacher demographic characteristics (e.g., age, gender, race, ethnicity, country of birth, primary language spoken in the home, English proficiency, years of education) will be collected via the JS Demographic survey. We will use specific study questions from the RADx Common Data Elements to measure **vaccine uptake and confidence**.[62] Given the

disproportionate impact of COVID-19 on Black and Hispanic populations[68], these factors as well as other demographics and vaccine confidence will be examined as covariates.

2.5.3 Aim 3

Adoption of center-wide policy pillars including COVID-19-related practices will be assessed quantitatively by the HERS-Program-level at all 5 time points. The HERS-P includes the same domains as the HERS-C but is focused on center policies. 1) Safety (physical safety and disaster recovery procedures), 2) Trauma-informed Behavioral Supports (teacher-child relationships, structured environment, social-emotional program practices), 3) Self-Care (staff support and supervision), and 4) Communication (teacher-parent communication and connection). This observational measure will be completed by trained RAs who have established inter-rater reliability. This is a primary outcome measure.

Key informant interviews Semi-structured interview guides will be developed based on available COVID-19 literature[69] and the results of the HERS to assess implementation barriers and facilitators and to inform necessary toolkit or cultural adaptations. Two graduate-level RAs will conduct interviews by phone or videoconference at T1, T2, T3, and T5 with a subset of directors, teachers, and parents until saturation is achieved in each of the block randomized centers to ensure equal ethnic composition of Hispanic and non-Hispanic Black participants.

Societal contextual variables outside of the centers' control (e.g., population surge in cases by zip code, vaccine access and uptake by staff and children if authorization provides, self-reported infection), will be measured by the COVID-19 Impact Survey, the RADx COVID-19 Common Data Elements.[62]

2.6 Data Analyses

Quantitative data analysis will test for the minimal detectable effect size for intervention

effects for the first two research aims based on an a priori power analysis, for child and

teacher/classroom level outcomes measures. Minimum detectable effect sizes were estimated

based on prior evidence of child- and teacher-level effects in pilot studies.[70,71]

Aim 1 will use multilevel and latent growth modeling to examine short- and long-term

effects of the intervention versus control condition, on child behavior problems, prosocial

behaviors, and executive functioning skills. To account for the nested data structure in the

cluster-randomized design, we will use multilevel models. Latent growth models (LGM) will

examine the long-term maintenance of intervention effects on children's outcomes over time

(from baseline to 24 months). The Johnson-Neyman technique will assess moderating effects of

child and family risk variables (e.g., child behavior problems and parent stress) that could

influence children's outcomes.[72]

Aim 2 will use multiple regression and latent growth modeling to examine differences in

trajectories of teachers' classroom practices, attitudes (self-efficacy) and beliefs (job stress,

coping, distress) between the 2 conditions (intervention and control groups) and over the 5

assessment time points. The LGM will control for teachers' baseline sociodemographic variables

by specifying those as covariates at level 2.

Aim 3. Similar to other hybrid designs, we will assess implementation using an

exploratory sequential mixed methods approach or one in which qualitative data are used to

explain quantitative findings.[73,74] This approach has been informative in prior Type 1

implementation-effectiveness studies to explore barriers/facilitators as well as potential societal

contextual factors (e.g., vaccine uptake) to help centers serving disproportionately affected

minority communities recover from and prepare for future crises.[73] This ensures that the JS+CS toolkit is responsive to the needs of racially and ethnically diverse childcare providers, is perceived as valuable, and is adaptable to the broader community/policy context.

We will first examine data collected from the HERS-Program level to determine a) overall implementation adoption (average total HERS score) and b) implementation adoption of each JS+CS pillar (average HERS score by domain). We will categorize scores as either "meeting implementation standards" (i.e., HERS score ≥5) or "not meeting implementation standards" (i.e., HERS score <5). The focus of our qualitative interviews will be based on quantitative findings. For centers whose scores show they are meeting vs. not meeting implementation standards, interviews will focus on implementation facilitators vs. barriers to the intervention, respectively. Given the evolving nature of COVID-19 guidelines, we will employ a rapid qualitative analysis approach to summarize main points from key informant interviews into matrices and explore relevant themes. Although there are different RQA approaches, we will follow the steps described by Hamilton [5] which involve developing brief summary documents to summarize key points from interviews, transferring the information into matrices to view data across all participants and all domains of interest, and using a matrix analysis approach to explore relevant themes. This process has been recommended to address rapidly evolving, urgent health equity challenges[76] and will allow us to analyze qualitative data efficiently and systematically. We will integrate the quantitative and qualitative findings by producing joint displays. Specifically, we will enter HERS-P scores into tables alongside qualitative findings and illustrative quotes, to compare quotes from centers who had scores indicating they were meeting vs. not meeting implementation standards.

3. Discussion

There are few available resources to aid centers in promoting psychosocial support to address the downstream psychological impacts of COVID-19 on teaching staff and children. The purpose of this study is to evaluate a multi-level public health intervention that will promote resilience while mitigating COVID-19's long-term impacts in these high-risk populations. To date, based on PubMed, there has been no rigorously tested research on the long-term impacts of COVID-19 on young children and staff in childcare centers or on interventions to mitigate the negative effects. Childcare centers are a population that have not traditionally been given support yet have been severely impacted by COVID-19.[77] The contribution of a novel multi-lingual intervention (i.e., English, Spanish, Creole) can have far reaching impacts for diverse communities across the country.

Georgetown University's Early Childhood Mental Health Consultation is an evidence-based multi-level intervention with documented short- and long-term effects.[63,78,79] At the center level, it provides quality supports for staff and children.[78] At the teacher level, it improves resilience by helping them develop strategies to overcome teaching challenges, strengthen self-efficacy, reduce stress, and improve classroom practices.[78,80] At the child level, it improves child resilience by increasing prosocial skills and executive functioning.[78] JS+CS adapted the Georgetown Model during the COVID-19 pandemic to provide virtual support by promoting self-care and improving coping strategies needed at the child, teacher, and center levels. The effectiveness of this virtual program will be evaluated using this RCT. Evaluation of the telepresence robot consultation approach is vital for understanding how to best support teachers during public health crises. Virtual consultation reduces travel time and allows access to rural and remote centers, which increases consultants' capacity to serve more centers in need. Kubi

technology is an affordable telehealth option that can be adapted to diverse clients and settings beyond childcare centers.

As with all community-based research, there are anticipated barriers, such as treatment noncompliance (withdrawing or moving to a non-participating or control center). In the event of treatment non-compliance, the causal estimates of interest will be the intent to treat (ITT) and the treatment-on-treated effects. In addition, given this is a technology-based intervention, teachers who are not comfortable with the use of technology may have difficulty accessing services. In order to overcome this barrier, we will assemble a step-by-step technology guide on how to troubleshoot various scenarios as well as short video demos for teachers. The consultants will be well-versed and trained in troubleshooting, and technology support specialists on the team will be available for additional assistance. Lastly, measurement tools needed to be considered. Specifically, given the limitations of self-report, we have intentionally included multi-method measures, such as observational measures at the center-, classroom-, and child-level. Barring these challenges, the results of this study will provide insight on how to best prepare childcare centers and build their capacity to respond to subsequent public health crises and provide children with life-long coping skills.

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Declaration of interests

☒ 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.

☐The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: